Commercialization of Health Products from Sub-Saharan Africa: Challenges and Opportunities.

By

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A thesis submitted in conformity with the requirements for the degree of Doctor of Philosophy

Institute of Medical Sciences
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Abstract

Despite the global progress made in improving health of people and increasing the life expectancy, Sub-Saharan Africa continues to be plagued by many health problems. Commercialization of health products from Sub-Saharan Africa presents opportunities to solve some of these health problems as well as generate economic returns. This thesis explored science based health product commercialization in sub-Saharan Africa through three studies. The objective was to identify opportunities and challenges facing health product commercialization in Sub-Saharan Africa. A qualitative case study approach was used and data collected using interviews. The first study involved looking at science based health product commercialization at a national level. Rwanda was chosen for this study. Thirty eight key informants selected from various institutions that form the health innovation system in Rwanda were interviewed. The results of the study show that opportunities exist in Rwanda for health product commercialization mainly because of the strong political will to support health innovation. However the main challenge is that there are no linkages between the actors involved in health innovation in Rwanda. The second study looked at health innovation at the level of a research institution. The Kenya Medical Research Institute (KEMRI) was studied where eight key informants were interviewed. The results show that KEMRI faced many challenges in its attempt at health product development, including shifting markets, lack of infrastructure, inadequate financing, and weak human capital with respect to innovation. However, it overcame them through diversification, partnerships and changes in culture. The third study looked at health technologies that are being developed in sub-Saharan Africa but have stagnated in laboratories. Thirty nine key informants were interviewed. A total of 25 technologies were identified, the majority being traditional plant medicines; other technologies
identified included diagnostic tests and medical devices. Many of these technologies require further validation. Other key challenges to commercialization of these technologies that were identified included a lack of innovative culture among scientists and policy makers and lack of proof of concept funds including venture capital. Overall, this thesis identified opportunities for science based health commercialization in Africa, and also provides recommendations on how to overcome major challenges.
Acknowledgements

No matter how far a stream flows, it never forgets its source. As I end this chapter of my academic journey, I cannot but fully express my joy at surviving the PhD. I am cognizant of the fact that this would not have been possible without the encouragement and support of many outstanding individuals who anchored me all the way. This word of acknowledgement can scarcely say how truly thankful I am to you all. You were guardians and angels.

Let me begin by addressing a special thanks to you, Dr. Peter Singer, my supervisor, whose direction, valuable advice and technical input helped shape this thesis. You probably do not have an idea how much your accurate and insightful comments on the study, journal submission, manuscript revision or your endless e-mail questions motivated me to complete this journey. Although you had a lot of other work, you always managed to have time to encourage me. Your commitment to ensure I succeed in my PhD journey including providing funding support from the Canadian Institutes of Health Research grant and your Michael Smith award has left a lasting legacy on me. I cannot sufficiently express my gratitude. Thank you.

To you, my committee members, Profs Abdallah Daar and Anita McGahan, you were a source of inspiration. You supported me enthusiastically and your thought-provoking comments made me go the extra mile that enhanced the academic quality of this thesis.

Special thanks goes to you, Daria Smeh. You were always interested in my PhD stories. You not only provided words of encouragement but made a lot of sacrifices for me, especially in the last deadline months when you proof-read and edited the entire thesis. You amazed me how you managed to contribute to the often “heavy research stuff” and your comments and suggestions were really helpful in getting this PhD dissertation in its final shape. You are indeed a dear friend. To Grace Nzainga, I also want to thank you. I never imagined that you, a planner would be the one to shape my research question.

When I begun this journey, I never knew I would find family here in Toronto. In the McLaughlin-Rotman centre for Global health I found a community that made me feel at home. To you my peers, my fellow graduate students, I would like to express my profound gratitude. To Monali for your constant hugs, stories and friendship and for consoling me whenever I was frustrated; Dominique for your patience while entertaining even my most trivial questions; Billie-Jo for leading the peer group and encouraging us to focus; Andrew Kapoor for reminding me to always ride the donkey instead of carrying it; Mark for your constant reminders not to let my social endeavours distract me from the prize; Lara for being a good neighbor and Rahim for your comic jokes. You guys inspired me to walk this journey as you gave me daily support and put things in perspective. You filled my days with laughter, entertainment, moments of joy and encouragement whenever I was low.
My memories go to my departed friend, fellow graduate student and buddy Sara Al-Bader. Sara, you were a great source of inspiration to me. You touched me in a very special way. Your down-to-earth attitude encouraged me and your comments on my thesis and insistence on academic rigour significantly raised the quality of this thesis. Though the cruel hand of death prevented you from seeing the final thesis, know that you will forever be in my memory.

Andrew Taylor, Sina Zere, Beatrice Seguin and Leticia Law; I would like to thank you for your administrative support that enabled me carry out my research seamlessly. To Obidi, my colleague, thank you for assisting me with my presentation.

To my extended family here in Canada, the Abeingo community, you provided the warmth that enabled me focus on my studies. Special thanks to you Joseph Mulongo for welcoming me to Canada and sharing your PhD experience with me. To my buddies, Edwin, Chris, Nimo and Grace and many others who provided me with the social support necessary to concentrate on my studies, I also say thank you. Those weekends at Crocodile rock, Hemingway’s and Fox and Fiddle provided the spice that prevented me from going insane. I had a great time for sure!

A special word of thank you goes to you Pam, for being a dear friend. You not only provided technical input, helped me with formatting but endured my endless telephone calls with trivial questions.

But none of this would be possible without the support of my family. First of all, I thank my parents. You always wanted to get the best out of me. Mum, you taught me to reach high and not to ever give up before I reached my goal; just the qualities I needed to fulfill this PhD journey. Dad, you made me who I am. You taught me to put things in context, which is certainly needed in the world of academic research. Furthermore, I appreciated the interest and the support of my sisters Ruth, Catherine, Doris, Mary and Jaqueline as well as my brothers Bob and Fred and their families. Special gratitude goes to my nephew Brian and my niece Eva. You have been the perfect family.

Last but not least I want to thank the almighty God for giving me good health and strength to complete this journey. But more importantly Lord, I thank you for bringing all these angels and guardians who made this journey possible.
Dedication

To all African scientists…the world is yours to explore
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LIST OF ABBREVIATIONS

ANDI  African Network for Drugs and Diagnostics Innovation
DALY  Disability-adjusted life year
DNDi  Drugs for Neglected Diseases Initiative
GDP  Gross Domestic Product
HAT  Human African Trypanosomiasis
HIV  Human Immunodeficiency Virus
IFC  International Finance Corporation
IP  Intellectual property
ISAR  Institut des Sciences Agronomiques du Rwanda
KEMRI  Kenya Medical Research Institute
MRA  Medical regulatory authorities
NEPAD  New Partnership for Africa's Development
NGO  Non governmental organizations
NIS  National Innovation System
NMR  Nuclear magnetic resonance
OECD  Organization for Economic Co-operation and Development
OTC  Over-the-counter
PCT  Patent Cooperation Treaty
PRO  Public research organizations
R & D  Research and Development
RIS  Regional Innovation System
S & T  Science and Technology
SIS  Sectoral Innovation System
SME  Small and Medium size enterprises
SSA  Sub-Saharan Africa
<table>
<thead>
<tr>
<th>Abbreviation</th>
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<tr>
<td>TB</td>
<td>Tuberculosis</td>
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<tr>
<td>UNCTAD</td>
<td>UN Conference on Technology and Development</td>
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<tr>
<td>UN</td>
<td>United Nations</td>
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<tr>
<td>US</td>
<td>United States</td>
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<tr>
<td>VC</td>
<td>Venture capital</td>
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<td>VCT</td>
<td>Voluntary testing and Counselling</td>
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<td>WEF</td>
<td>World Economic Forum</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Chapter One: INTRODUCTION

1.1 Research problem

There have been vast improvements in life expectancy and reductions in childhood mortality globally in the last century (World Bank, 2010). This reduction has mainly been attributed to improvements in nutrition, living standards, housing, sanitation and the diffusion of medical innovations, notably immunization and antibiotics. Despite this, sub-Saharan Africa (SSA) continues to suffer from ill-health due to infectious diseases, largely as a result of poor access to health products as well as from environmental health conditions (Tumushabe & Mugabe, 2009). Malaria, tuberculosis (TB), and HIV annually account for 1 million, 600,000 and 500,000 deaths, respectively; and are attributed to over 80% of the disease burden. Overall, life expectancy in Africa fell from 58 year in 1980 to 46 in 2003, mainly due to HIV (NEPAD, 2003).

Like in many developing countries, the economic losses due to the disease burden and healthcare expenditure in Africa are enormous, with malaria estimated to cost over 12 billion US dollars per year in terms of treatment and lost working days (Sachs, Gallup, & Mellinger, 2001). Other economic losses include lost labor-force productivity, business disruption, and the costs of treatment for people whose exposure to the disease could have been prevented e.g. mother to child transmission of HIV ((NEPAD, 2003).

A report prepared by the African Network for Drugs and Diagnostics Innovation (ANDI) in 2009 captured this poor health situation in Africa and attributed it to a complex combination of reasons including the inadequacy of the health systems in Africa which often lack medical personnel and are poorly equipped (ANDI, 2009). Freedman, et al (2005) described the African health systems as the source of catastrophic costs, humiliating treatment, and deepening social exclusion (Freedman et al., 2005). But additional factors amplify this sorry state and include the absence, lack of access or the
inappropriateness of existing health products to prevent, diagnose and treat some of the health conditions (ANDI, 2009).

According to the ANDI (2009) report, part of the reason that the situation is complex is the type of diseases found predominantly in Africa. According to the report, some diseases, like HIV and sleeping sickness (Human African Trypanosomiasis) have simply no treatment or available treatment that is accessible is toxic. And in the case of Malaria and TB, no vaccines have been developed. But in many cases, it is simply a matter of lack of access to medicines in general. The report further states that the vast majority of the population in Africa relies on the government to provide health care yet resources are limited. This has resulted in less than 50% of the population having access to essential medicines. Access is also limited because health facilities are often located in urban areas, far away from rural populations which tend to have more need. There are few doctors (less than three doctors per 10,000 in most countries) and poor infrastructure such as roads, transportation, electricity and lack of clean water supply further exacerbate the situation (ANDI, 2009).

Storage and distribution systems are non existent or are poorly managed, resulting in significant losses of medicines. The World Bank estimates that for every $100 spent by African governments on drugs, only $12 worth of medicines reaches patients (World Bank, 2004). Long duration and complexity of treatment of diseases common to Africa (e.g., for TB and Leishmaniasis) reduces treatment compliance, which, combined with drug misuse\(^1\), has led to development of resistance rendering current treatment useless (Wright et al., 2009).

Another issue cited by authors that results in the poor health indicators is that affected patients represent a low-priority market for Western pharmaceutical manufacturers. Overall, only 13 new drugs have been developed for neglected tropical diseases since

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\(^1\) Drug misuse is mainly as a result of poor or self-diagnosis resulting in the use of drugs even when not necessary.
1975, out of the 1,556 new chemical entities marketed between 1975 and 2004, with, for example, only four drugs - albendazole, oxamniquine, praziquantel, and ivermectin - being developed to treat helminthiases (Beard, 2009; Chirac & Torreele, 2006; Hotez et al., 2008).

Costs of available essential health products are also beyond the reach of most people in sub-Saharan Africa, where out of pocket expenditures constitute 91%-100% of private health care costs in a majority of countries yet 38.2% of the people live below the international income poverty line of US$ 1 per day (IFC, 2007). For example, a full dose of the WHO recommended standard treatment of malaria i.e. artemisin-combination chemotherapy\(^2\) costs over 5 US dollars (WHO, 2010). Even when products are subsidized, the top-up costs is still a financial hurdle for many Africans. For example, mosquito nets are considered a long-lasting effective intervention to prevent malaria. However, the top up price for a mosquito net hovers around one dollar which is unaffordable to many Africans. As a result, widespread use of nets is reduced, yet they have been shown to significantly reduce the incidence of malaria (Mulligan, Yukich, & Hanson, 2008).

The high prices of medicines encourage the emergence of a black market whereby counterfeiters thrive. Approximately 30% of the medicines sold in African countries are counterfeit (Chauve, 2008). These counterfeits can be harmful to the health of patients as in most cases they contain actively harmful ingredients, including talcum powder, sawdust, paint and an array of other toxic or inert substances, not just false placebos (Cockburn, Newton, Agyarko, Akunyili, & White, 2005; Newton et al., 2006). Fake medicines also contribute to the emergence of drug resistance to diseases ranging from HIV and malaria to tuberculosis, increasing the overall costs of treatment (Bate, Coticelli, Tren, & Attaran, 2008; Olliaro & Taylor, 2010). Further, drug resistance, due to misuse

and compliance issues has meant that effective treatment for diseases such as for malaria, tuberculosis (TB), schistosomiasis or bacterial dysentery has effectively been rendered useless.

Where medical devices exist, they are often not appropriate for African settings. Some diagnostic examinations of common African diseases require complicated technological skills. For example, diagnosis of sleeping sickness requires examination of cerebro-spinal fluid obtained by lumbar puncture (Ndung'u, Bieler, & Roscigno, 2010); additionally diagnosis of Leishmaniasis requires demonstration of the parasite in a biopsy sample or tissue aspirate of the spleen or the bone marrow, while diagnosis of TB requires examination of a sputum smear (WHO, 2010). These require significant technical skills, training and logistics and can often only be done in hospital settings. Sometimes the technology can be simple, such as the use of long-lasting mosquito nets now widely available in Africa, but there then arises an issue with houses in which a normal net cannot be hung because space is insufficient.

The health care challenge further extends to vaccines. Low immunization is the number one cause of infant mortality. About 59% of pregnant women in Africa deliver babies away from health facilities. Although home deliveries can be safe in a sanitary environment, deliveries in health facilities mean immediate and more likely access to vaccinations. Many African countries have vaccine coverage below 50 % making it the region with the lowest rate of on-time immunization in the world (Kirigia & Barry, 2008). Besides accessibility issues, most available childhood vaccines have stringent storage and shipment cold-chain requirements unavailable in most rural parts of Africa, meaning that the majority of the population cannot be adequately served.

There have been numerous attempts to address the problems of availability and accessibility to health technologies in Africa. The number of drugs in development for neglected diseases has increased and funding for research and development (R & D) for neglected diseases has increased significantly. In 2008, almost US $3.1 billion was
invested in this area, with HIV/AIDS, malaria and tuberculosis initiatives comprising close to three-quarters of this investment (Moran et al., 2009). Incentives have also been provided for pharmaceuticals and institutions in the west to focus on diseases of the poor, including; Advance market commitments, product development partnerships, patent pools, prizes and others. The vast majority of the R & D support has gone to scientists in the west (Rudan et al., 2008).

Questions arise about the sustainability of this trend where most research and development has been going to the west (Frew, Kettler, & Singer, 2008; Hecht, Wilson, & Palriwala, 2009). Simply importing western-developed technologies to Africa has not succeeded in alleviating the health burden that affects most of these countries (Chataway et al., 2009). Even with incentives, western pharmaceuticals and research institutions continue to prefer researching in diseases common in their countries. The result is the often mentioned “10/90 gap” phrase, where 90 % of overall research and development dollars are spent on health products for the wealthy, while only 10 % is spent on the diseases of the poor continues to widen (Currat, de Francisco, Al-Tuwaijri, Ghaffar, & Jupp, 2004).

Part of the reason that most of the recipients of funds have been in the west is that their research capabilities are known. Analysis of scientific publications, which is one of the most reliable indicators of scientific capacity, reveals the predominant position that western scientists hold in research and development (Schubert & Telcs, 1986). But R & D capabilities of countries and institutions in sub-Saharan Africa - both in internalizing foreign health innovations and, in developing their own home grown ideas and translating these into products and services- are largely unknown. In addition, the opportunities in health product commercialization and challenges that African governments, African research institutions and African scientists face in health product commercialization are largely unknown. Yet this knowledge is important for a variety of reasons: attracting investment, developing appropriate technologies that could provide a solution to the dismal health problems identified above; reducing reliance on imported technologies;
directing investment to those who have long-term personal investments in a region or country; innovation towards local health problems, and providing new economic opportunities.

### 1.2 Gaps in the literature

It is clear that health problems and the capacity to address them in sub-Saharan Africa is complex and clearly will require a multi-dimensional response. It has also been shown that it is not just an issue of availability of health products, but issues like appropriateness of existing technologies to the African context complicate the entire approach to address health care issues. Innovation in new tools and new approaches to tackle these problems is definitely required.

Considering the increasing enthusiasm for domestic African health innovation as a panacea for the variety of health problems, research to inform its practice is important. However, gaps in the literature on African innovation in general and health product commercialization in Africa in particular hinder a complete understanding of the situation and how to address it. And even where there is literature, it contains a number of evident voids there require further development.

While there are case studies on health innovation in emerging economies e.g. India, and China (Frew, Kettler, & Singer, 2008), Brazil (Rezaie, Frew, Sammut, Maliakkal, Daar, & Singer, 2008) and Cuba (Thorsteinsdóttir, Sáenz, Quach, Daar, & Singer, 2004), the literature does not reveal any in depth country case studies on science based health innovation in Africa except on South Africa (Al-Bader, S. 2009). Most case studies on innovation in Africa have been too general (i.e. not limited to health) and have been in form of surveys; Kenya, Uganda and Tanzania (Oyelaran-Oyeyinka, 2007). Surveys tend to be abstract and skeletal, providing a limited understanding of how organizations and institutions involved in research, R & D, product development and marketing function or relate to each other. In many cases, details are overlooked and much of the conceptual
apparatus around systems of innovations approaches does not provide decision making clarity.

Adopting an ethnographic approach and a research strategy of first-hand field research, description and interpretation ensures that the richness of a case is captured (Maanen, 1983) resulting in an analytical induction of various phenomena (Bengtsson, Elg, & Lind, 1997). This study approach could lead to valuable insights and explain health innovation in Africa which may enable policy makers make appropriate decisions to improve science based health product commercialization.

There are few studies in the literature on health product development in Africa (Chataway et al., 2009; Sampath & Oyelaran-Oyeyinka, 2007). Despite the central role that public research institutions and universities in Africa play in health innovation (Oyelaran-Oyeyinka & McCormick, 2007), scholars have largely ignored studying factors that affect health product commercialization in these institutions nor their strategies to commercialize products. A search of the literature using the Web of Knowledge did not reveal any studies that specifically look at strategies that health research institutions in Africa adapt to commercialize their health products. An in depth look at how research institutions in Africa can commercialize their research is therefore necessary.

Many scholars have correctly stated that innovation leads to new products and new processes, among others (Freeman & Soete, 2007; Lundvall, 2010; Oyelaran-Oyeyinka, 2006). And that product development is at the core of innovation. But save for documentation of types of plant medicines found in Africa e.g. (Kilama, 2009; Okigbo & Mmeka, 2006), the literature is blank on health products that are being developed in Africa. This is a serious void, because policy discussions on health product commercialization in Africa will depend on whether there are indeed health products that can be commercialized. By scoping some of these technologies and providing in depth
Authors agree that it is wrong to imagine that innovation in developing countries is the same as in the developed world. There are many divergent views on what constitutes innovation in the context of Africa depending on perspective (Oyelaran-Oyeyinka, 2006). Aubert, (2005) for example states that innovation in developing countries constitutes three forms: 1). Local improvements based on the adoption of technologies which are more or less available worldwide; 2). locally adaptations made to existing technologies and 3) design and production of novel technologies (Aubert, 2005). Edquist, (2005), suggests that innovation in developing countries is more product focused than process focused, while other authors, including Frew et al (2007) suggest that innovation in developing countries is both product and process focused. In addition, Edquist suggests that for developing countries, innovations in low and medium technology sectors are more attainable than those in high technology systems (Edquist, 2005). Frew et al go further to suggest that innovation in developing countries revolves around affordability (Frew, Kettler, & Singer, 2008). None of these authors offer empirical testing in the African context to support their proposition. However, overall these divergent views of what constitutes innovation in developing countries and in Africa, necessitates further analysis and is one gap that this study seeks to contribute towards filling.

While the amount of literature on innovation in general has more than doubled in the last five years, information gaps persist on many aspects of innovation in Africa and especially in health innovation. Thus, this thesis seeks to contribute towards filling this research gap by in-depth investigation of commercialization of science-based health innovation in sub-Saharan Africa, including biotechnology at three different levels; the National level, institutional level and technology level.

By science-based health innovation, I refer to technological innovation across a spectrum of sophistication, from vaccines, pharmaceuticals, and medical devices to a variety of
plant medicines where attempts have been made to scientifically standardize or characterize medicines. I take a broad definition of innovation as not only new-to-the-world, but also the diffusion, adaptation and use of technologies. I adopt the Oslo and Bogota Manuals definition of innovation, which is the internationally recognized standard for measurement of innovation (UNCTAD, 1996; Holbrook & Hughes, 2003). In this manual, innovation is defined as “the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organizational method in business practices, workplace organization or external relations” (OECD. 2005 p.46). The manual notes that the minimum requirement for an innovation is that the product, process, marketing method, or organizational method must be new or significantly improved to the firm or setting.

1.3 Research Question

The overall research question that guided this study is “what are the opportunities and challenges that exist in Africa at national, institutional and technological level towards commercialization of science based health technologies?”

To answer this question, I conducted three different independent studies in Africa. In the first study, the level of analysis was at national level. In the second study, the level of analysis was at institutional level. In the third study, the level of analysis was at technology level. Each study was guided by several sub-questions. The answers to the sub-questions in each study were then synthesized to provide an answer to the overall research question.

The sub-questions were as follows:

Study 1: National level. The purpose was to describe and analyze health innovation and biotechnology in a country. The main objective was to understand the actors, and the
system, highlighting its strengths and identifying its weakness. This objective was explored through the following research sub-questions:

a) What is the role of government as a facilitator and policy formulator in the system of health innovation?
b) What is the capacity of the country’s health research institutions for creating and undertaking research and development (R & D)?
c) What is the capacity and sustainability of the private sector to acquire and utilize local R & D outputs?
d) What is the role of foreign donors and international organizations in innovation in countries?
e) What are their linkages/interactions between actors in the system of innovation?

Study 2: Institutional level. The unit of analysis was a public health research institution. The main research aim was to analyze the commercialization environment – the microeconomic and strategic conditions – that the health research institution is facing in its attempts to translate ideas and technologies into products.

The sub-questions necessary to answer this were:

a) What is the organizational structure?
b) What is the institution’s research and development (R & D) capacity including examples of products being developed?
c) What is the organization policy towards Intellectual Property (IP)?
d) What strategies has the institution adopted regarding technology transfer either within the institution or eternally?
e) What are the challenges and barriers that hinder effective technology transfer?

Study 3: Technology level. The objective of this part of the study was to describe and analyze health technologies that may exist in Sub-Saharan Africa’s health research institutions but are not being commercialized. These non-commercialized technologies are referred to as stagnant technologies in this thesis. The sub-questions include:
a) What types of stagnant technologies are being developed in Africa’s research institutions including their uses and applications?

b) What are the barriers and challenges scientists in Africa face in their attempt to commercialize these technologies?

c) What strategies can be adopted to commercialize these technologies?

1.4 Research motivation

My desire to research health innovation in sub-Saharan Africa stems from my own journey as a researcher from Africa, an interest and appreciation in the experiences (and realities) of fellow African researchers, and identified gaps in the literature on this subject.

1.5 Significance of the study

This study has important practical implications. This knowledge will prove useful to a global audience of policy-makers, academics, entrepreneurs, and funding agencies. These series of case studies included in this thesis will help inform the effective development of innovation in Africa as follows.

- **Policy makers:** Such information will enable governments to promote an environment that will encourage scientists to become more innovative and commercialize their research, thus creating wealth and facilitate solutions to health problems. Such actions may include additional financing to scientists with innovative ideas, passing legislation that will promote innovation and protect indigenous scientific inventions, and creating proper institutional culture that facilitates commercialization.

  By showcasing that indeed such stagnant technologies do exist, the study will hopefully motivate other African governments to carry out their own technological audits to identify stagnant technologies that may be lying latent in their own backyards. It will also give them specific ideas of
how to commercialize these technologies, including examples of what has worked elsewhere.

- **Academics:** Lessons learned from these studies may be transferred to other African nations and academics in similar settings who can use them as teaching case studies in their institutions. Examples include schools of business and technology transfer offices in other similar institutions.

- **Entrepreneurs:** Information gathered from these studies will attract entrepreneurs as stagnant technologies so identified will present investment opportunities. The information will also include factors to consider before undertaking investment. They will thus be better informed when they make investment decisions hence minimizing risks.

- **Donor Agencies:** Donor agencies are an integral part of the health systems of these countries yet current investments are not yielding their intended outcomes. Knowledge of innovation systems of a country can enable donor agencies take appropriate initiatives that enhance innovative capabilities including promote relevant scientific research as well as promoting the establishment of dynamic linkages between institutions and private sector. They may also adapt new approaches to promoting commercialization, like making equity investments and venture capital.

Another implication from this research includes raising the profile of indigenous innovation that will help to challenge the idea that innovation only occurs at the technological frontier of rich economies. In turn, it can help African countries and particularly the private sector within them, to establish fruitful partnerships with local and international groups to build capacity and tap into the new sources of knowledge and know-how so important for growth.
1.6 Dissemination of this work

1.6.1 Publications

The following publications came directly from this study with my main contribution being participation in concept and design of the study, data collection and analysis and contributing to the manuscript development:


Data from this study also contributed to the following publications with my main contribution being participation in data collection and analysis, and contributing to manuscript development:


1.6.2 Conference presentations

Presentation of this work has been made at the following international conferences:

1. **Kenneth Simiyu** (2010). Barriers to health technology development and commercialization in Sub-Saharan Africa. *Biovision Alexandria 2010* (to be published online Dec 2010).


1.6.3 Workshops

Presentation of this work has been made at two workshops in Rwanda. The details of these workshops are discussed in Chapter 3.

1.7 The structure of the thesis

This thesis has seven chapters which are organized as follows;

Chapter one is the introduction. It introduces the research problem being studied and outlines the structure of the thesis. It also discusses the main gaps in the literature as well
as identifying the overall research question. It then gives a summary of the significance of the research to various different groups.

Chapter two is the literature review which situates the study within the wider literature, establishes the context and defines key concepts. It is divided into four sections. Section 1 lays out the theoretical argument using the wider innovations literature. This forms the basis of the conceptual framework through which we will understand this study. Section 2 discusses the application of the innovation systems literature in developing countries. According to the literature, innovation in developing countries is different from innovation in developed countries. Some authors describe innovation in developing countries as adaptation of technologies developed in the west to local settings. Others describe it as centred around affordability. Section 3 discusses the application of innovation systems literature on science based health innovation and tries to contrast it with other forms of innovation like engineering. In particular, the long length of time that it takes to bring health products to the market makes it risky and expensive. The final section discusses empirical literature on health innovation in Africa. It reviews available studies on innovation in Africa. It also identifies systemic weaknesses that characterize health innovation in Africa. The final section of this chapter gives a synthesis of the literature and summarizes the gaps identified.

Chapter three discusses the research strategy adopted for this study. The chapter discusses why the research design, which was a qualitative case study, was chosen. The chapter further describes case selection and how data was collected and analyzed. In addition, the chapter discusses the study limitations as well as issues surrounding ethical approval by the University of Toronto to conduct the study.

Chapter four and five and six are the results of case studies conducted at the national, institutional and technological levels respectively. These results are in the form of manuscripts reproduced in full that were submitted to different journals.
Chapter seven is the concluding chapter of the thesis which answers the overall research question that this study sought to investigate. This is done by integrating all the cases through synthesis of the answers to the sub-questions. The chapter also discusses the empirical and practical implications of the thesis on commercialization of health products from sub-Saharan Africa. Finally the chapter discusses the limitations of the study, provides suggestions on areas of future work and makes specific recommendations for policy makers.
Chapter Two: LITERATURE REVIEW

2.1: Introduction

This chapter situates the study within the wider literature, establishes the context and defines key concepts. It has four broad areas of literature that are discussed. The first section mainly discusses the theoretical literature on innovation and innovation systems in order to conceptualize the broad factors to be considered when discussing innovation. It also gives definitions of key concepts that will be used in the study. The section begins by defining innovation as the conversion of ideas into products of commercial value. Particular attention is devoted to explaining the various actors that constitute the national innovation systems approach.

The second section reviews literature on innovation systems of developing countries. Some recent studies have shown the difficulty of transplanting the innovations systems approach directly to developing countries (Ahrens, 2005; Dantas, 2005; Mani & Romijn, 2004). The main argument in these studies focuses on what constitutes innovation in the developing world context. It is generally agreed that whether it is new products or new processes, innovation in developing countries is centred on affordability.

The third section reviews literature on science based health innovation and biotechnology. Particularly noted in this section are the challenges faced by science-based health innovation and biotechnology. Unlike other sectors of innovation, science-based health and biotechnology innovation takes longer periods from idea generation to actual products; is high risk and hence does not easily attract capital; and is subject to rules and regulation which impact the development of products. Commercialization strategies that organizations adopt are also discussed here, with particular focus on open innovation. This section also reviews various approaches to technology development and commercialization that are currently being practiced, and looks at clusters, incubators and
science parks. It then focuses in on convergence centres, a model that was proposed by the McLaughlin Centre for global health in Africa and through which part of the study findings are being implemented.

The fourth part is a review of empirical literature on African innovation systems. The main objective of this section is to set the study in the context within which innovation takes place. The section begins by giving a brief socio-economic background of Africa and then looks at the typical features of what the various components of an innovation system are in Africa.

The final part of the literature review concludes with a synthesis of the literature review as well as a summary of the gaps identified in the literature that this thesis seeks to fill.

2.2 Innovation systems theoretical literature

There is general agreement among leading scholars that innovation can broadly be defined as the process that transforms ideas into commercial value (Edquist, 2005; Freeman & Soete, 2007; Lundvall, 1985; Lundvall, 2010; Nelson, 2000; OECD., 2005). Innovation includes discoveries made through R & D, but it also involves the knowledge and efforts of people in all business functions of an organization (sales & marketing, finance, operations, customer service, etc.). What is still not clear to many authors is whether innovation as defined in the western context is the same in the developing world, especially in Africa.

The definition of innovation can be drawn from the works of Schumpeter, whose ideas about innovation are widely regarded as having laid the foundation for innovation analysis (Freeman & Nickell, 1988). Schumpeter wrote in 1942 that innovation forms around technology or around markets (Schumpeter, 1942). He further posed that innovation was based on discontinuities in the entrepreneurial process of technological innovation.
Several later day proponents of innovation theory were inspired by Schumpeter’s work (Simmie & Kirby, 1998). The core features of his work were a) innovation is the main source of dynamism in capitalist economic development, b) historical perspective play important roles in understanding long-term economic change c) it is vital to distinguish conceptually between invention, innovation, and diffusion of innovation to analyze the long term effects of technological progress d) the importance of links between organizational, managerial, social, and technical innovations is key to understanding the system as a whole (Lundvall, 2010).

Other authors have attempted to build on the definition and understanding of the concept of innovation. Garcia and Calantone (2002) best captured the overall definition of innovation by reviewing the 1991 OECD definition of innovation. According to their analysis of this manual, innovation is “an iterative process initiated by the perception of a new market and/or new service opportunity for a technology based invention which leads to development, production, and marketing tasks striving for the commercial success of the invention” (Garcia & Calantone, 2002). This OECD definition, they said, distinguishes innovation into two components: [1] the ‘innovation’ process comprises the technological development of an invention coupled with the market introduction of that invention to end-users through adoption and diffusion, and [2] the innovation process is iterative in nature and thus, automatically includes the first introduction of a new innovation and the reintroduction of an improved innovation (Garcia & Calantone, 2002 pp 112).

Holbrook and Hughes (2003) in their review of innovation in the Oslo Manual suggested that it is partly derived from Schumpeter’s definition of innovation (Holbrook & Hughes, 2003). According to these authors, Schumpeter suggested that products for consumers result from a hierarchy of goods, services, and resources that make up productive forces. They write that these productive forces flow through the economy in a circular fashion, and whenever there is modification or disruption of the economic activity, either through
internal or external events, then the process of innovation is taking place. Their review notes that ideas need not be new to be innovative but can include the adaption of productive processes from one industry to create an advantage in another industry and the introduction of a product to a market in which it has not before been available. According to them, being the first to sell a product is what is innovative, not being the first to build a new product. Roger Martin (2010), states that while innovations are built around inventions, they are not one and the same thing. His argument is based on the premise that for something to be considered an innovation, it must add value to somebody’s life.

Many other authors have also based their discussion of innovation using Schumpeter’s arguments. Mytelka et al (2001) summarized the key features of various innovation theories (Mytelka, Smith, & Karelplein, 2001). The main thrust of the summary is;

a) Innovation is not restricted to any one sector
b) There are a wide range of innovation inputs some of which are non R & D
c) Innovation is not linear but rather it occurs through constant interactions between many players
d) Innovation involves a great deal of uncertainty
e) The behavior of firms is shaped by broader factors; the social and cultural context, the institutional and organizational framework, regulatory systems, infrastructures, the processes which create and distribute scientific knowledge.
f) The science system is important for innovation, and there is a strong interaction between technology and science. Although science does not provide the raw material for innovation in any simple way, it remains a key element of industry knowledge bases across the economy.

This thesis is guided by the OECD’s Oslo Manual (2005) definition of innovation which is the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organizational method in business practices,

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workplace organization or external relations (OECD. 2005 p.46). The Oslo manual states that the minimum requirement for an innovation is that the product, process, marketing method, or organizational method must be new or significantly improved to a particular setting. This includes both innovations that are pioneering for an organization, as well as those adopted from other settings but adopted to different environment. In developing countries innovation may consist of incremental changes, acquisition of embodied technology, and applications or adaptations of existing products or processes (Lall & Pietrobelli, 2005).

2.2.1 Innovation systems

A systems approach to the analysis of economic and technological change has formed the main framework for understanding innovation for decades (Godin, 2009). This was mainly in response to failure by economists to integrate institutions in their econometric models. The earlier systems approach began with Freeman, who in the 1960’s, put forward the proposal that systems, already useful at that time for military purposes, could be adapted to the needs of civilian industrial technology (Freeman & Soete, 2007).

Since then, many different variations of the system’s approach have emerged which include, the National Innovation System, NIS (Lundvall, 2010; Edquist, 1997; Edquist, 2005; Nelson, 1993; Lundvall, 1985; Freeman, 1995), sectoral and technological innovation systems (SIS) (Malerba, 2006), and regional innovation systems (RIS): (Asheim & Gertler, 2005; P. N. Cooke, Heidenreich, & Braczyk, 2004; Doloreux & Parto, 2004; Doloreux & Parto, 2005). These approaches are similar and only differ, on the most part, on how the boundaries of the system are determined. These boundaries are continuously evolving and may transcend sectoral or technical boundaries. Thus NIS delineates the boundary to be the nation state. On the other hand, SIS defines the unit of analysis as those organizations that are interdependent across the nation or region and operate in the same product market (Malerba, 2006). The concept of RIS is closely
related to regionally identifiable nodes or clusters of industrial activity (P. N. Cooke et al., 2004).

In his evaluation of the systems approach, Godin (2009) posits that the main objective of a systems approach was that it suggested better theorizing of institutions, rules, and culture, as well as promoting their integration into technological analyses (Godin, 2009). Further, the concept of a system of innovation, Godin adds, brings together “in a single framework the interactions and linkages between knowledge creators, distributors and users of technology, and how they affect productivity, competitiveness, and economic and social development”. Entrepreneurs, policy-makers, researchers, workers, and consumers are all part of the innovation system. The emphasis is on interactions and the influence of policy. Identifying and strengthening the constituent parts of an innovation system is the basis of studying innovation systems.

From the literature, determining the appropriate systemic framework for understanding innovation depends on several analytical and methodological issues. Carlsson et al (2002) suggest that the choice depends on the purpose at hand, the population (actors) to be studied as well as the measure of performance of the system. Thus it depends on whether you are analyzing a technology, a cluster of activities or firms—and for what geographic area (Carlsson, Jacobsson, Holmén, & Rickne, 2002).

In this thesis, I will use a systems approach to analyze innovation science based health innovation and biotechnology. A system of science based health innovation and biotechnology is composed of actors, institutions, organizations and policies that together support innovation in health and biotechnology, along with the infrastructure and financing mechanisms that enable it (Chataway et al., 2009). While the characteristics of these health innovation systems may differ between (and even within) countries and necessitates country-specific studies; there remain basic issues that are common to most African countries.
At the core of an innovation system are knowledge and information flows between the various components that are multidirectional in nature (UN, 2009). Part of these knowledge flows are influenced purely by market forces whereby the nature, direction and speed of research is determined by demand. Demand also affects the decision on which technologies will be developed. On the other hand, knowledge flows can also be enhanced through targeted policies and investments.

2.2.1.1 National innovation systems (NIS)

The innovation system bound by national borders is referred to as the National System of Innovation (NIS). Several international organizations including the OECD, World Bank, World Economic Forum (WEF) use the NIS concept as an integral part of their analytical perspective on innovation (Lundvall, 2010). The UN Conference on Technology and Development (UNCTAD) also emphasized the usefulness of the NIS to study innovation in developing countries by recognizing that for innovation to take place there has to be interactions between several actors (Holbrook & Hughes, 2003).

Overall, the concept of a national system of innovation has also influenced how technological performance and innovative capacities of countries are studied (Freeman, 1995; Lundvall, 2007; Lundvall, 2010; Nelson, 1993; Nelson, 2000). It has been noted that even though globalization was taking place, national and regional systems of innovation remained an essential domain of economic analysis (Freeman, 1995).

Lundvall, (2010) carried out a review of the works of various authors on the national innovation system concept (Lundvall, 2010). These authors use geopolitical boundaries as their framework for analysis. In national and regional variants, geo-political boundaries are used to define the organizational and regulatory environment in which invention, innovation and diffusion of new products, processes and services take place. This approach enables scholars to take into account the limitations of macro-economic processes of growth that otherwise do not take into consideration the role played by
institutions, and the interactions between them, to transform the economic and social landscape. Because it emphasizes the structural conditions that promote the creation and transfer of knowledge, both tacit and codified, it clearly demonstrates the major source of competitive advantages for economies, industries and firms.

The NIS is about how institutions interact to generate and use new products, processes and organizational practices i.e. flows of technology and information among people, enterprises and institutions are key to the innovative process (OECD, 2005; OECD, 2002). The intensity and effectiveness of the interactions will largely determine the output of the innovation system. Socio-economic surroundings, political surroundings, culture and other societal and historical elements determine how it develops.

2.2.1.1.1 Essential features of a National innovation system

The NIS consists of many actors; the main institutional actors being universities, public R & D institutes, policy-making bodies and the government in general, private enterprises, financial institutions such as commercial banks, and technology support agencies. Understanding the linkages and interactions among the institutional actors involved in innovation activities or processes is crucial to improving a country’s technological and economic performance. Additionally, the NIS approach offers a more realistic picture of development processes because it views innovation efforts as intimately linked to broader macroeconomic and educational policies (Feinson, 2003).

Other elements of a national innovation system include government research and innovation priorities, government policies for R & D and innovation, quality of scientific research institutions, public and private sector investment in R & D, protection of intellectual property, institutional linkages particularly university-industry collaborations, availability and utilization of skills in science, engineering and entrepreneurship fields, existence and use of technology standards and regulatory agencies, and nation’s participation in regional and international programmes. In developing countries other
actors include non governmental organizations (NGO’s), donors and members of the diaspora.

In this section, I will briefly look at some key features of the NIS.

a). Innovation environment
b). Government policy
c). R & D activities
d) Private sector firms
e) Finance
f) Intellectual property
g) Regulatory environment

2.2.1.1.1 Innovation environment

The innovation environment in the country affects innovation because it determines the ability of markets to operate freely. The innovation environment is the circumstances that allow ideas to be properly nurtured and developed. These circumstances include sound educational opportunities, a system that rewards ingenuity, favourable investment incentives, protection of intellectual property and ensures safety and benefits of new products. Strong innovation climates enhance innovation while weak ones tend to inhibit innovation. In the global competitiveness report by the WEF (2010), factors that affect innovation include: government procedures, including the ease of doing business, excessive bureaucracy and red tape, over regulation, corruption, dishonesty in dealing with public contracts, lack of transparency and trustworthiness, and the political dependence of the judicial system (World Economic Forum., 2010). In addition, the report suggests that the quality of institutions established by the government has a strong bearing on innovation as it influences investment decisions and the organization of production and plays a central role in the ways in which societies distribute the benefits and bear the costs of development strategies and policies. These institutions, which also include conflict resolution mechanisms like an independent judiciary, will determine
whether people can feel secure to invest in land, corporate shares, or intellectual property. The government also develops the legal and administrative framework in which innovation occurs and prioritizes how individuals and firms interact among themselves and with the government (World Economic Forum, 2010).

2.2.1.1.2 Government policy

The important role that government policy plays in science, technology and innovation has been recognized by many authors. For example, Juma et al, (2004) in their analysis of biotechnology in Africa underscore the importance of how government policy influences innovation (Juma & Yee-Cheong, 2004). In another discussion on the role of government in national innovation systems, Metcalfe and Ramlogan (2008) use policy themes to suggest that there are two major ways that the government policies influence innovation (S. Metcalfe & Ramlogan, 2008). First, government policies towards education and investments in public research and development affect innovation. These policies affect the level of available skilled personnel necessary to carry out innovation as well as the research orientation in the country. How closely these skills are aligned to innovations that are emerging at the frontier of science will determine how successful the country is in adopting innovations. More specifically, government’s influence research orientation by directing resources into particular areas of new research and supporting particular institutions in line with the government’s scientific strategy (Kaiser & Prange, 2004).

Secondly, Metcalfe and Ramlogan (2008) suggest that governments also create and oversee the rules of interaction in an innovation system. Government influences flow of knowledge and people within the innovation system as well as enabling the system to connect with international knowledge groups, something that is essential for the dynamism of an innovation system. The government can play a role in securing technology licenses for testing as well as establishing collaboration between countries (Nelson, 2004). Some of the interactions that the government facilitates include
university–industry linkages and linkages between public research organizations (PRO’s) and users.

Explicit government policies including policy documents, science advising structures and funding also influence innovation (Juma & Yee-Cheong, 2004). For example in the US, which is the leading nation in innovation, the Bayh-Dole Act, which allows for the transfer of exclusive control over many government funded inventions to universities and businesses operating with federal contracts for the purpose of further development and commercialization served to accelerate commercialization of innovations from universities. Several countries, including India, Brazil, South Africa, Malaysia, and Jordan, have come up with different variation of legislation modeled on the U.S. Bayh-Dole Act (Graff 2007).

Similarly, Japan enacted a new Basic Law for Science and Technology (S & T) in 1995 to try and develop a more cohesive and forceful government S & T policy whose main aim was to strengthen cooperation between industry, universities and government research organizations. Government commitment can also be seen by the percentage of GDP committed to R & D. For example government support for R & D in China is evident from the fact that R & D spending has grown by 22 per cent a year since 1996. Israel spends more than 4 per cent of GDP on R & D; Finland, Japan, South Korea, and Sweden spend more than 3 per cent; Austria, Denmark, Germany, Iceland, Switzerland, Taiwan, and the United States spend more than 2.5 per cent and Australia spends 2 per.

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4 The exact text of this act can be found at http://www.law.cornell.edu/uscode/html/uscode35/usc_sec_35_00000200----000-.html
6 http://www8.cao.go.jp/cstp/english/law/law.html
7 This information was got from http://www.innovation.gov.au/innovationreview/Documents/PoweringIdeas_fullreport.pdf
Almost all governments have developed S & T policy documents that guide innovation in their countries. The aim of these documents is mainly to set the priorities of innovation as well as link them to a country’s development strategy. Partly because of the diversity of actors in a system, these policy documents act to as a link between supply and demand sides (Metcalfe, 2005; Smits & Kuhlmann, 2004).

2.2.1.1.3 R & D activities

The term Research and Development (R & D) is often used when discussing a country’s innovation capacity. Referencing the Frascati Manual (OECD, 2002), ‘R & D comprises creative work undertaken on a systematic basis in order to increase the stock of knowledge to devise new applications’ (OECD, 2002).

Early R & D activities in industrial countries took place in public universities and public research institutes (Lalkaka, 2002). This link between university research and the private sector in the US has been well documented in the literature (Rosenberg & Nelson, 1994). Military related R & D expenditures dominated early research expenditures. Resultant innovations then spilled over for civilian use. In the United States, in the early years, military R & D and space/nuclear power programs were the main R & D activities enabling technologies (Mowery, 1992a). Semi-conductors, that now form the foundation of the modern electronic industry, were an example of technologies that were developed for military purposes but spilled over to civilian use (Holbrook, Cohen, Hounshell, & Klepper, 2000).

There are no established rules in measuring R & D capacities, and it is even more difficult in developing countries as there is usually lack data (Gaillard, 2010). R & D activity involves three broad areas; i.e. basic research, applied research and experimental development which occur sequentially resulting in a product that is useful to consumers.
R & D results in both codified and tacit knowledge which is then used in the creation of new innovations (Haruyama, 2009). However, determining levels of research and development in a country is not straightforward (Chataway et al, 2009). Nonetheless, though it has its limitations (Gaillard, 2010), measurement of scientific publications is widely used as one of the reliable indicators to measure scientific capacity of a country (Schubert & Telcs, 1986).

This thesis will focus on organizations and institutions that devote the majority of their efforts in the various stages of research, development, technology transfer and commercialization of health products.

2.2.1.1.4 Finance

In his study of the economics of innovation, Schumpeter conceptualized the importance of financial resources to innovation (O’Sullivan, 2004). He focused on two different but related units of analysis in demonstrating the links between innovation and resource (Schumpeter, 1911). He emphasized the role that financial intermediaries play in innovation i.e. institutions that allocate financial resources and manage risk.

The relationship between cash flow and innovative activity has subsequently been examined by many authors and a review done by Hall and Lerner (2009) shows that most authors have established that there is a positive relationship between these two variables (Hall & Lerner, 2009). Finance has been shown to be important to the overall innovation process as there are many costs associated with innovation besides R & D. These include market analysis, actual product development, legal and organizational costs as well as costs of hiring the right staff skilled in innovation management. Once the commercial potential of an idea has been identified, exploiting that potential requires significant financial, technical and managerial investment (UN, 2009).
But it is also acknowledged that R & D and innovative activities cannot be solely financed in a freely competitive market place (Hall & Lerner, 2009). Part of the difficulty arises due to the characteristics of R & D investments which are different from any other investment. First, R & D requires investment in highly skilled manpower. R & D relies heavily on tacit knowledge rather than codified knowledge, meaning that the risk of losing the investment when an employee leaves is high. Many firms thus are hesitant to make this investment. Secondly, there is a great deal of uncertainty related to R & D investment. These investments typically take a long time to know the output. Uncertainty is greatest at the beginning, but could extend to the entire duration of the project.

Financial needs of innovative enterprises vary but finance is needed from seed stage, early growth, start-up and the expansion phase. A report by the United Nations Economic Commission for Europe (UN, 2009) identified the major sources of finance for innovation as follows;

a) Family and friends: Personal funds of the founders as well as of their families are usually the quickest source of early stage financing but these are usually insufficient to meet the financial demands for development of an innovation. Some founders may take out personal loans because some financial institutions deem such ventures high risk, hence are not willing to finance the innovation. They also require collateral hence these funds are limited.

b) Competitive awards: e.g. grants. Usually provided by public (government) agencies, mainly to support their broader social objectives for innovation and economic development.

c) External equity: These include business angels and venture capital (VC) funds (including private, corporate affiliates, or government-sponsored). These funding sources have been discussed extensively in literature with many authors explicitly stating that the type of funding an investment will attract will depend on the stage of establishment of the firm and type of activity that it is engaged in (Bertoni & Grilli, 2005).
Business angels – where individuals provide risk capital directly to small, private, often start-up firms – (Prowse, 1998) is another source of funding that is available to support innovation. Angels are often wealthy individuals with entrepreneurial background. Prowse (1998) described them as “the second round of financing after an entrepreneur has exhausted all his family and friends' money, but before he approaches formal venture capital partnerships” (Prowse, 1998).

The important role that venture capital plays in funding innovation has also been recognized by many authors e.g. (Kõomägi & Sander, 2006; Smith & Smith, 2000). Venture capital – which refers to provision of finance, managerial oversight and strategic expertise to enterprises with ideas whose commercial viability is deemed real – (Bertoni, Colombo, & Croce, 2010) is often the only source of finance for high risk and small start-up companies. It has catalyzed new business models in the developed world and is considered by many authors as the best source of funding for technology-based companies (Bertoni, Colombo, & Grilli, 2008). Companies such as Google, Microsoft and Genzyme were developed using venture capital. Venture capitalists provide capital in exchange for the allocation of controlling shares of the firm. Most of the venture capitalists are private enterprises though governments have provided venture capital to fund early start up businesses. In most developed nations, the availability of venture capital has been responsible for the emergence and subsequent business flourishing of most SMEs (Ahlstrom & Bruton, 2006).

Analysis based on empirical data has for decades raised questions about whether many VC firms require excessive shares of a company’s growth in exchange for their up-front investments, and add sufficient value to justify their fees (Bygrave & Timmons, 1992). However, VC’s have indisputably been key catalysts in the success of many companies that are now household names, and they bring a range of strengths to developing new science-based businesses. Venture investors can help to identify promising early-stage
opportunities, invest into opportunities too risky for banks, support development of new firms, and network new firms with markets and mentors (Gompers & Lerner, 2004). They develop specialized expertise to select, monitor, and support investments, and thus reduce risk for investors into VC funds. The value of these risk-reduction functions may be even greater in developing countries. Venture investors may thus be able to identify promising opportunities from basic R & D, and transform them into viable products and services – supplementing public funds by channelling private capital toward global health innovation.

2.2.1.1.5 Private sector Firms

In OECD economies, the private sector firms are the main performer of research and development and source of innovation (OECD, 1997). This is especially true in fields such as biotechnology and information technologies, where development costs are particularly high. This situation is similar in the United States, where most innovations still emerge from the private sector (Mowery, 1992).

The role that private sector firms and entrepreneurial activity play on innovation has been traced back to the writings of Schumpeter. Breschi et al (1997) stated that Schumpeter proposed two models: Mark 1 and Mark 2. In the Mark 1 model which he proposed in his 1912 book “The Theory of Economic Development”, the small innovative entrepreneur is the key agent of innovation and is motivated to innovate in order to gain substantial market share, maintain it over time, and edge out less successful firms (Breschi, Malerba, & Edquist, 1997). Many of these small entrepreneurs compete among themselves, resulting in a cascading effect that leads to clustering of such entrepreneurs. New products and processes are diffused, but as the innovations mature competition forces prices to reduce, leading to reduced profits and, as a result, the entrepreneur has to become innovative again to survive.
A review by Breschi et al (1997) of Schumpeter’s Mark 2 model published in the book *Capitalism, Socialism and Democracy (1942)* states that it is large monopolistic firms that are responsible for innovation. This review suggests that from Schumpeter’s viewpoint innovation is enhanced by increased investment in industrial research, and the bureaucratized process of technological change. The review further shows that innovation is restricted to a small group that is able to increase R & D intensity. This model is characterized by patenting that leads to monopoly rents (Breschi et al, 1997). Similarly, Henderson and Cockburn (1994) noted that investment in innovation is affected by the size of the firm with larger firms being able to invest more as their overheads are lower (Henderson & Cockburn, 1994).

Lundvall (2010) also referred to Schumpeter’s work and suggested that according to Schumpeter, in a market economy, innovation was embodied in new firms and that these firms were usually driven by entrepreneurs who were “new”; that is, who were not already prominent in business circle (Lundvall, 2010).

2.2.1.1.6 Intellectual Property

Intellectual property (IP) influences innovation by allowing the creator, or owner of a patent, trademark, or copyright to benefit from his or her own work or investment (Cotropia, 2010). OECD broadly defines IP as “the legal rights associated with creative effort in a certain industry and includes computer programs, films, designs, inventions, artistic and literal works etc” (Liberti, 2010). The positive relationship between IP and innovation has also been documented by the OECD (OECD, 2007). The benefits of IP protection have also been discussed by many authors e.g (Cornish & Llewelyn, 1989; Merges, Menell, Lemley, & Jorde, 2003). Analysis of the literature also reveals that
society benefits if unauthorized copying and distribution of ideas is prevented as it encourages innovation⁸.

The most common way of protecting IP is patenting and patent citations are still the best measure of innovation (OECD, 2007). Other ways of protecting innovation include trade-secrecy, copyright laws and trademarks. Patent system for protecting inventions varies across countries and industries⁹. Although the procedures for patent rights are governed by the rules and regulations of international and regional treaties, governance of patents is territorial i.e they are only valid in countries that they are filed. Patents are filed by making applications to country patent offices. They can also be filed internationally using the Patent Cooperation Treaty (PCT)¹⁰ route for international filing strategies. Using the PCT route not only buys time, at a small cost, but may also provide cost savings in the future if it is finally decided to pursue patent protection in a smaller number of countries than was originally envisaged.

Individuals, companies or institutions patent their inventions as a way of protecting them and also to recoup the costs of their investment. Costs include information searches, patent drafting, patent office costs as well as patent protection. In addition, because patents are territorial, the costs multiply for every country covered by it. However, not every patent is commercially viable and hence it makes most sense to patent only when there is reasonable suspicion that profits from an invention will recoup the cost of obtaining patent protection.

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⁸ See, e.g. , U.S. CONST.art.1 § 8 (giving the United States Congress the power to grant patents and copyrights in order to “promote the Progress of Science and useful Arts”); Mazer v Stein, 347 U.S 201, 219 (1954) (“the economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare…”)


¹⁰ The Patent Cooperation treaty states that all members will cooperate in the filing, searching, and examination, of applications for the protection of inventions, and for rendering special technical services. http://www.wipo.int/pct/en/texts/articles/a1.htm#_1
IP policies are well developed in developed countries but some developing countries are still struggling to institute IP policies. In developing countries, IP policies are designed to encourage the influx of foreign technology but as a country’s technological capability improves, protection shifts to development of domestic capability. Institutions and universities also develop intellectual property policies and thus create a system where inventions with commercial potential are commercialized (Rosell & Agrawal, 2006). These Institutional intellectual property policies outline ownership of inventions between institutions and inventors.

2.2.1.1.7 Regulatory environment

The impact of regulatory frameworks established by the government on innovation has also been discussed in the literature (Ashford & Heaton Jr, 1983; Magat, 1979; Stewart, 1981). The government’s institutional structures affect the rules under which actors in the innovation system interact and influence the incentives and opportunities to innovate. In the telecommunications industry, for example, there are authors who argue that increased regulation of mobile wireless services would enhance innovation while other authors argue that they would have the opposite effect (Ehrlich, Eisenach, & Leighton, 2010).

One of the fundamental components of an innovation system is product regulation. Products are regulated to meet certain standards that ensure high quality to consumers. The setting of standards has resulted in the development of many innovations and the diffusion of both product and process technological changes (Ashford, Ayers, & Stone, 1985). Additionally, technological advances have resulted from product-focused regulation as new products substitute older ones which have been banned by regulation. Thus, it is clear that regulation can have a positive effect and has been a key driver of many innovations.

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11 The banning of lead in gasoline resulted in the development of new products and new processes.
Drugs and medical devices are also subject to stringent regulation usually by medical
drug authorities whose role is to ensure the quality, safety and efficacy of all medicines.
Regulatory agencies including environmental regulations also influence innovation as
products should not have deleterious effects on the environment.

Regulation can also be in the form of trade tariffs and these have been shown to be
associated with R & D intensity (Bassanini & Ernst, 2002). Trade barriers prevent the
importation of certain products, stimulating domestic firms to develop products that will
substitute for imported ones.
2.3 Innovation systems in developing countries

Despite being the most common approach to studying innovation, several authors e.g Erbil, (2007), Mani (2004), Dantas (2005), Ahrens (2005), Lall & Pietrobelli (2003) etc have discussed the difficulties of applying the NIS to developing countries (Ahrens, 2005; Dantas, 2005; Erbil, 2007; Lall & Pietrobelli, 2003; Mani & Romijn, 2004). The main argument of these authors is that external factors greatly affect a government’s ability to execute autonomous policies.

Innovation systems are complex, and should not be generalized between countries (Metcalf & Ramlogan, 2008). Consequently, when analyzing innovation in developing countries it is important to distinguish the difference with developed countries. The NIS approach has been greatly emphasized in explaining economic development in emerging economies like China and South Africa (OECD, 2007). These examples have been made into blueprints for prescribing development through innovation for countries that are at relatively lower levels of economic development. However, many socio-political factors as well as a nation’s history shape innovation in developing countries and hence the national innovation system may be different in developing countries. Indeed, while cross-border exchanges may influence activities, technological development remains nation-specific.

In many cases, direct transfer of Western consumer products to developing country markets is not commercially successful. For example, attempts by Unilever to sell consumer products like margarine, ice cream and convenience foods imported from the west to developing countries were not successful due to various facts including dietary differences, availability of electrical power and the absence of a buoyant middle class (Jones, 2010). Multinationals are thus forced to develop products that are suitable for different markets.
Government policies in developing countries may not directly influence the type of innovation in firms e.g. R & D of multinational companies will be influenced by their corporate strategy rather than be subjected to the policies of the developing country. But governments may dictate that foreign companies develop local factories in order to gain entry into those markets. These local factories usually result in local innovations on products as the demands of the market are easier to understand. An example is in Mexico, where the American beauty company Avon was required to do this resulting in innovative beauty skin products (Jones, 2010). In India and South Korea establishment of local subsidiaries of multinationals led to the development of many innovative products ranging from software to detergents that targeted the domestic population.

2.3.1 Innovation environment in developing countries

The World Economic Forum, (2010) and the World Bank (2005) describe the innovation climate in developing countries as one characterized by major structural weakness mainly due to weaknesses in the essential components of a knowledge economy (Aubert, 2005; World Economic Forum, 2010). The major weaknesses cited by these reports are the weak education attainment levels in most such countries resulting in low skilled manpower; the business environment is hampered by poor financial transparency and a top-heavy bureaucratic environment. As well, poor infrastructure, especially low telephone and internet penetration, further compounds innovative capacity. Nonetheless, the recent surge in mobile telephony in developing countries has alleviated some of the problems12.

In addition, the innovation climate is also affected by political meddling and corruption whereby political influence may be used to obtain favours or bar rivals thus stifling innovation.

12 For a detailed look at innovation in developed countries, see Measuring Innovation: A New Perspective OECD Paris, 2010.
2.3.2 Nature of innovations in developing countries

The broad definition of what constitutes innovation in developing countries continues to be a subject of discussion between scholars, sometimes with diametrically opposed views. The divergent views by authors have been attributed to various factors including difference in focus (product or process) and national origin of the author (Johnson, Edquist, & Lundvall, 2003).

Aubert, 2005 has categorized innovation found in developing countries into three forms taking into account the local context: the first form relates to “local improvements based on the adoption of technologies which are more or less available worldwide or locally (“technology adoption” from a global perspective)”. The second type of innovation “materializes in the building up of competitive activities with some adaptation made to existing technologies (“technology adaptation”).” And finally, the third type of innovation is “the design and production of technologies of a worldwide significance” (Aubert, 2005).

Edquist, (2005) suggests that because of structural weakness in their innovation system, most developing countries start by importing existing technology and creating the internal capabilities to utilize and improve on those technologies before starting to develop their own novel technologies. Using the term closing the “technological gap” with developed countries, he states that innovation in developing countries has the following characteristics; Product innovations are more important than process innovations because of effect on the product structure; Incremental innovations are more important and attainable than radical ones; Absorptions (diffusion) is more important than development of innovations that are new to the world; Innovations in low and medium technology sectors are more attainable than those in high technology systems (Edquist, 2005).
The importance of absorptive capacities was also advanced by Feinson, (2003). Feinson suggests that “developing nations rely on “absorptive capacities,” or their “ability to [acquire,] learn and adopt the technologies and associated practices of already developed countries” (Feinson, 2003).

However, other authors have increasingly recognized that innovation in developing countries is focused around cost reduction and affordability of existing products. In a study of the Indian biotechnology firm, Shantha Biotech, Frew et al (2008) found that affordability was their main contribution to innovation (Frew, Kettler, & Singer, 2008). This firm realized that reducing the cost of the Hepatitis B vaccine was crucial for it to reach more people in India and thereby developed innovative processes that reduced costs. Similarly, a study of the Brazilian biotechnology sector also revealed that cost reduction was an important consideration in innovation (Rezaie, Frew, Sammut, Maliakkal, Daar, & Singer, 2008). At the same time, in Cuba, the Finlay Institute developed a purified meningococci vaccine in the mid 1980’s that was the first of its kind worldwide and was affordable (Thorsteinsdóttir, Sáenz, Quach, Daar, & Singer, 2004).
2.4 Science based health innovation and biotechnology industry

The literature reviewed for this thesis shows that science as a business has been a focus of many scholars. Pissano’s (2010) summary of the challenges that science-based businesses face i.e (i) managing and rewarding long-term risk, (ii) integrating across technical disciplines, and (iii) learning (Pisano, 2006) captures the issues that other authors have raised on science as a business. This section will review how scholars have discussed some factors that are unique to science based businesses especially with regards to health product development.

2.4.1 Science based health R & D

The literature notes some commonalities and some marked differences between science-based health R & D and R & D in other sectors. As a result, there is a learning potential from the literature and from other R & D sectors. The depth by which they differ is as a result of several factors chief among which is the long and expensive development times needed in science based health R & D due to patenting, clinical tests, regulations etc. Nwaka et al, 2009 state that the discovery of novel drug leads with the potential to become usable medicines is long (typically 10 to 15 years), costly (between US$500 and US$800 million), and technically challenging (Nwaka et al, 2009). Many of the research projects trying to produce novel products fail to even yield any product.

In this section, the literature on phyto-pharmaceuticals and biotechnology are the two categories of science based health innovation that are discussed followed by an analysis of factors that affect innovation in this industry.
2.4.1.1 Phyto-pharmaceuticals

Many traditional plant medicines are used as starting points in the drug discovery process (Fabricant & Farnsworth, 2001). The use of traditional plants as a means of therapy dates back to the Middle Paleolithic age some 60,000 years ago early civilizations (Solecki, 1975). The World Health Organization has estimated that about 65% of the world’s population uses plants as their source of medicinal agents, with the global herbal market estimated to have a market value of about US$ 62 billion a year\(^\text{13}\). However, in addition to use of whole herbal remedies, plants are an important source of bioactive compounds for direct use as drugs, e.g. Digoxin, Digitoxin, Morphine, Reserpine as well as being used to produce novel entities of lead compounds for semi-synthetic processes (Fabricant & Farnsworth, 2001). Other examples of drugs that have been obtained from plants include Artemisinin that is used to treat malaria, codeine for the treatment of common colds and flu’s and strychnine that is used as a pesticide to kill small vertebrates etc.

All countries in the world have traditional plant medicines and can commercially exploit them. The main advantage of traditional plant medicines as the starting point in any drug development program is that since they have been used by human for a long period of time, (often for hundreds or thousands of years), the WHO recommends that they be exempt from some stages in the drug discovery process as they will have already shown low human acute toxicity (Fabricant & Farnsworth, 2001). This hastens the process and also reduces costs. In addition, when metabolized, the secondary products may be equal or superior to that found in synthetic chemical entities. Since the ultimate goal of the drug discovery process is to produce synthetic compounds with low toxicity and higher efficacy, plants are a good source of lead compounds negating the need to isolate novel synthetic products.

\(^{13}\) as estimated by Dabur Research Foundation
Nonetheless, there are still some issues about the potential variability in plant chemistry and resulting biologic activity. There is still controversy on whether you can patent naturally occurring products like plant material (Farnsworth, Bigel, Wagner, & Wolff, 1977).

2.4.1.2 Biotechnology

Biotechnology is defined as “the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services” (OECD, 2005b). The emergence of biotechnology in the mid 1980’s transformed the life sciences industry (Belussi, Sammarra, & Sedita, 2010). This is because it gave rise to new tools that enabled scientific discoveries and allowed researchers to explore complex biological processes and diseases in agriculture and health. Biotechnology has also had significant application in chemical and pharmaceutical companies. Biotechnology has led to development of a billion-dollar industry in the world, with biotech drugs accounting for 24% of the 2007 pharmaceutical market sales growth of $35 billion (Lawrence, 2007).

Biotechnology has significant use in research, therapeutics and manufacturing in health fields (Lawrence, 2007; Clark & March, 2006). Biotech research and development has led to the discovery of new medications and more efficient pharmaceutical production methods.

It has led to the development of several products, first beginning with human insulin, and then followed by block-buster drugs, including the cancer drugs, Epogen® and Avastin®. Other biotechnology drugs include treatments for autoimmune disorders that target tumor necrosis factor and combination anti-retrovirals for HIV. In 2002, researchers announced successful results for a vaccine against cervical cancer, the first demonstration of a preventative vaccine for a type of cancer.
In addition, biotechnology has many applications in global health which include new vaccines and drugs, efficient delivery methods and novel approaches to therapeutics (Acharya, Kennedy, Daar, & Singer, 2004; Daar et al., 2002). New diagnostics tools, which have global health implications, like those for tuberculosis, AIDS, and papilloma virus have been developed based on biotechnology. These tools are rapid, cheaper and more accurate. In addition, many biotechnology tests are portable, have higher sensitivity and specificity, are rapid and can easily be done at the point of care. Most of these tests rely on visually-read results, thus can be performed by staff without extensive training.

Innovative biotech products relevant to local settings have been produced in many developing countries. Examples include the meningitis B vaccines in Cuba (López et al., 2007; Thorsteinsdóttir, Sáenz, Quach, Daar, & Singer, 2004), a tablet formulation of cholera vaccine in China (Frew et al., 2008; Frew, Kettler, & Singer, 2008), a cost-effective manufacturing process for hepatitis B vaccine in India (Frew, Kettler, & Singer, 2008); and vaccines and diagnostic tests in Brazil (Castro & Barros, 2009; Rezaie, Frew, Sammut, Maliakkal, Daar, & Singer, 2008). South Africa, with other global partners, has been using biotechnology to try and develop a vaccine against the type of HIV most prevalent there (Al-Tuwaijri et al., 2004). These products are having tremendous impact on the lives of millions of people in the developing world. Biotechnology applications for more than 200 diseases including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS, and arthritis are also undergoing clinical trials globally.

Not all authors are of the view that the biotechnology industry has been successful. Pisano (2006) argues that despite biotech having provided promising health products, the industry is still faced with many challenges (Pisano, 2006). He states that an industry that is purely motivated by profits ends up compromising on science hence the reason why there have been fewer innovative biotechnology products over the last few years.
2.4.2 Key factors that influence Science based health innovation and biotechnology

2.4.2.1 Financing of science based health innovation

While the literature reviewed for this thesis shows that there is no agreement on the true cost of health product development, especially pharmaceutical drugs, there is general consensus that the cost is high. For example, Tyfield (2008), speculates that the cost of producing a drug in the 1960’s averaged $5 million to develop, which grew to $25 million in the mid-1970’s and then grew to $100 million in 2003 (Tyfield, 2008). Yet another review by DiMasi et al (2003) estimated that the total R & D cost per new drug in 2000 was US $ 802 million in 2000 (DiMasi, Hansen, & Grabowski, 2003). Grewal et al (2008), estimate that the cost is about $800 million–$1 billion per drug (Grewal, Chakravarty, Ding, & Liechty, 2008). These three studies, though varying, show that health R & D is costly.

Traditionally, there have been two major sources of health R & D financing; public and private funding. Governments continue to be the major source of finance for research and innovation in science based health innovation especially at the initial stages of basic research. In the United States, for example, federal funding makes up more than half of the total funds devoted to basic research in public institutions like universities and other non-profit research organizations in 2010\textsuperscript{14}. It is also the same in the European Union, Canada and the emerging economies (Wolfe, 2005). Usually, public funding is given to medical research councils such as the NIH in the United States, the Medical Research Council in Great Britain, and the Agence Nationale pour la Recherche Scientifique in France which then give grants to academic researchers through competitive grant

programs. The aim of public funds is to help develop ideas and promising health technologies are then transferred to drug companies. These drug companies then provide private finance to carry out additional research and to translate research results into commercially viable products. The source of private financing can be venture capital, shareholder equity, debt issued by the company (bonds), and internally generated revenues from sales of other products.

In regard to global health innovation, the last decade witnessed increased finance by many actors including G8 nations, the United Nations agencies, the Global Fund and philanthropists like the Bill and Melinda Gates Foundation and Multilateral donors like the IFC and the World Bank (Ravishankar et al., 2009). More than 1 billion US dollars have been invested by philanthropists and donors into global product development partnerships (PDP’s) and these have shown great progress in the development of innovative products needed in global health (Morel et al., 2005). Direct financing of global health innovations is also being carried out by many others including the G8 nations, the United Nations agencies, the Global fund and philanthropists like the Bill and Melinda Gates Foundation and Multilateral donors like the IFC and the World Bank (Ravishankar et al., 2009). Other initiatives that have emerged to help finance innovation in management of diseases affecting the developing world include Advance Market Commitments, product development partnerships, patent pools, prizes and others.

Academics and entrepreneurs consider venture capital as the best source of private funding for technology-based companies like health and biotechnology (Ackerly, Valverde, Diener, Dossary, & Schulman, 2009). In the developed countries, venture capital was used to pioneer health products in such companies like Genentech (hormones), Amgen (hormone epogen), Genzyme, Aviron (Vaccines), Adolor and Neurogesx (pain therapy), Alnylam Pharmaceuticals (RNAi therapy) and GenVec (Gene therapy).
2.4.2.2 Legal and Regulatory framework in science based health innovation

Unlike other fields of innovation, science based health innovation is greatly impacted by legal and regulatory issues. This is primarily because it affects the human body. Regulatory functions are usually performed by country medical regulatory agencies whose function is to ensure product quality, safety and efficacy of all medicines in circulation in their country, including regulating and monitoring their clinical development, manufacture, approval for marketing, distribution, procurement, import, export, supply, sale and promotion (Kessler, Pape, & Sundwall, 1987).

Medical regulatory agencies carry out technical assessment of health products to ensure that all medical products sold in the country are safe, then register them and give them marketing approval or marketing authorization. Drugs for Neglected Diseases Initiative (DNDi) commissioned a report that looked at MRA’s in Africa and concluded that drug regulation is challenging to developing countries especially when it comes to pharmaceuticals (DNDi., 2010). The report mentions that technical difficulty increases from simple generic drugs, to new formulations and fixed dose combinations (FDCs) with novel drugs and biological products such as vaccines being the most difficult of all to assess.

There have been concerns that having different medical regulatory agencies have different standards for products will compromise the quality of products especially when it comes to cross border trade. The WHO cited these varying discrepancies between the different country regulatory agencies as a major hindrance to uniform regulation of medical products and commissioned the establishment of the Global Harmonization Task Force (GHTF) in 1992 which proposed the harmonization of medical device classification (see www.GHTF.org document SG1/N015R18)\(^\text{15}\). In September, 2010, the

\(^{15}\) http://www.ghtf.org/
task force recommended the establishment of uniform standards for auditing manufacturers of medical devices (see document GHTF/SG4/N84:2010)\textsuperscript{16}.

2.4.2.3 Intellectual property and science based health innovation

Science based health innovation research is costly, lengthy, and high-risk and yet individuals and companies have to recoup their investment. In order to achieve this, they have to use patents on new drugs to gain market exclusivity for a limited period. These fees are also needed to fund further research.

Many questions on the impact of intellectual property on science based health innovations have been raised by many authors (Gold, Kaplan, Orbinski, Harland-Logan, & N-Marandi, 2010). It is argued that intellectual property in science based health innovation has had the impact of increasing costs of medicines (Saha, Grabowski, Birnbaum, Greenberg, & Bizan, 2006), thus greatly affecting their availability to patients in the developing world (Attaran, 2004; Lanjouw, 2005). The same applies to medical devices, where patented improvements in performance and safety of existing devices limit the entry of competitors, driving up costs up (Gold et al., 2010).

Other authors are of the view that research and development in life sciences also becomes more expensive for the simple reason that researchers and companies hoping to modify processes or use existing ideas for innovation must clear patent rights to do their work (Cho, Illangasekare, Weaver, Leonard, & Merz, 2003; Gold et al., 2010). Researchers may require permission to use patented reagents, to try a patented method, and/or use a patented device.

\textsuperscript{16} http://www.ghtf.org/documents/sg4/sg4final_n84.pdf
2.4.2.4 Commercialization of science based health innovation from universities and public research institutes.

Health product commercialization has been described as an orderly series of steps; building a prototype, testing its feasibility, and progressing to complete product development and design (Gans & Stern, 2003a). The traditional pathway for developing new health products begins with public research institutes as generators of knowledge, and the private sector as the translator of the knowledge into actual ventures.

Product commercialization is defined as conversion of an idea or technology to a product or service that generates profits or has an impact on the lives of everyday people (Gans & Stern, 2003). In the developed world early product commercialization is driven by public research institutes and universities (Godin, 2009). Notable health products commercialized this way include the Boyer–Cohen “gene-splicing” technique that launched the biotechnology industry and diagnostic tests for breast cancer and osteoporosis (Siegel, Waldman, & Link, 2003).

In the developing world, health products developed in public institutes and then transferred to the private sector include the first effective meningitis B vaccine, developed at the Finlay Institute in Cuba, licensed to Glaxo SmithKline and the antimalarial drug arteether (a semi-synthetic artemisinin derivative), developed at India’s Central Drug Research Institute, now licensed to Themis Chemicals and sold in 48 countries (Morel et al., 2005).

A review of literature reveals that technology commercialization strategy is becoming an important issue in operating public research institutes. Won, (2004) observed that technology commercialization strategies of public laboratories can be classified into the following six categories. 1) contracting R & D to industrial partners; 2) working with industrial consortia; 3) licensing to industry; 4) influencing key decision makers; 5) working with broker organizations; and 6) generating end-user demand (Won, 2004).
2.4.2.4.1 Open innovation and commercialization of science based health innovation

Won (2004) further identifies several reasons that hinder commercialization of technologies developed by public laboratories, especially in developing countries. First, there is a predominant focus of public laboratories on basic research, not on product development in general. Second, if technologies are developed the research is directed towards technologies that must be developed, regardless of cost-effectiveness and market needs. Third, the technologies involved are intended for specific missions, usually public needs rather than market needs. Finally, the lack of experience of public laboratory managers in product development also hinders commercialization (Won, 2004).

Won’s observation are similar to Chesbrough (2003) who first proposed the open innovation concept by suggesting that organisations are increasingly resorting to open innovation strategies to augment the variety and speed of knowledge flows essential to innovation (Chesbrough, 2003). Chesbrough’s open innovation concept proposes that “firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as the firms look to advance their technology” (Chesbrough, 2006). West and Gallagher built on that definition and stated that open innovation is “…systematically encouraging and exploring a wide range of internal and external sources of innovation opportunities, consciously integrating that exploration with firm capabilities and resources, and broadly exploiting those opportunities through multiple channels” ((West & Gallagher, 2006).

The concept of open innovation as a commercialization strategy is increasingly given prominence in literature on science based health innovation. Cohen and Levinthal (1990) suggested that firms in the high-tech sectors of science based health innovation (biomedical, biotech, pharmaceutics and computer science applied to the medical fields) show a systematic access to external knowledge sources (Cohen & Levinthal, 1989). Other authors who have made similar observations that organizations are increasingly
relying on open models include Baum et al (2000) and Niosi (2003) who suggest that science based health innovation firms’ innovation strategy develops within open models (Baum, Calabrese, & Silverman, 2000; Niosi, 2003). Arrow, (1994) states that since science based health innovation relies a lot on the creation of new knowledge, it is inevitably linked to public research (R & D projects on basic research) developed within the scientific institutions, and collectively shared (Arrow, 1994). The crucial interchange of knowledge between knowledge creators (public research institutes) and firms in science based health innovation was also recognized by Cooke (2007), who argued that firms cluster where there are public research institutes to use knowledge generated from them (Cooke, 2007).

While the natural tendency of firms is to protect their innovations through patents, they are forced to adopt an open model due to the necessity of acquiring complementary production abilities, technological capabilities and customers from other organizations (Belderbos, Leten, & Suzuki, 2009).

Other insights on academic-industry transfer of knowledge have also been provided by Agrawal (2003) who attributed the difference in commercialization success across private sector firms on the different strategies they employ to license university inventions and suggested that engaging the inventor directly and early in technology development is the best way to ensure commercial success (Agrawal, 2006). Owen-Smith et al (2002) compared the successful academic-industry knowledge transfer systems of the US to that of European countries and recommended that it is important for European countries to first establish protocols that foster collaboration with industry before mirroring the US system (Owen-Smith, Riccaboni, Pammolli, & Powell, 2002).

2.4.2.4.2 The role of Clusters in commercialization of science based health innovation

Scholars have described how clustering or groupings of research organizations and entrepreneurs and other actors that integrate innovation and development work helped to
propel innovation in developed countries (Delgado, Porter, & Stern, 2010). The cluster idea, which was first framed by Alfred Marshall in 1872, has been defined as “geographic concentrations of interconnected companies, specialized suppliers, service providers, and associated institutions in a particular field that are present in a nation or region” (Porter, 1998). The concept can be summarized as an “agglomeration of actors that combine resources to gain a competitive advantage in innovation” (Owen-Smith, Riccaboni, Pammolli, & Powell, 2002). Common cluster examples cited in the literature include; Information and computer technologies; Silicone Valley, CA; Austin, Texas, Route 128, MA; the Auto industry and related products and services: Detroit, MI & Windsor ON; Turin, Italy; Nagoya, Japan and the Motion picture industry: Hollywood, CA; Rome Italy, Paris, France.

Three broad ways in which clusters foster innovation were identified (Porter, 1998); they increase the productivity of companies based in the area; they drive the direction and pace of innovation; they stimulate the formation of new businesses within the cluster. Porter further suggested that “geographic, cultural, and institutional proximity provides companies with special access, closer relationships, better information, powerful incentives, and other advantages that are difficult to tap from a distance. The more complex, knowledge-based, and dynamic the world economy becomes, the more this is true. Competitive advantage lies increasingly in local things--knowledge, relationships, and motivation--that distant rivals cannot replicate” (Porter, 1998).

Owen-Smith et al (2002) have attributed the successful knowledge transfer between US academic institutions and private sector industry to biomedical clusters. They use the example of the biomedical cluster around the Boston area that groups together Dana-Farber, Harvard University, and Massachusetts Institute of Technology (MIT) and many other small firms around Boston to illustrate this significance. In addition, as the clusters grow, they become linked to others not necessarily located in close geographical proximity (Owen-Smith, Riccaboni, Pammolli, & Powell, 2002).
While clusters are predominantly geographical, there are many other variations that use the same concept. These include:

a) Business incubating centers
b) Science (technology) parks
c) Convergence Centers

2.4.2.4.2.1 Business Incubators centers

An essential part of product commercialization is the creation of small- and mid-sized firms. Business incubators play a role in their creation as well as providing affordable space and providing core business support functions, such as business development, financing, marketing, and legal services to start up enterprises (Ratinho & Henriques, 2009).

Through focused help to selected firms, business incubators have the added benefit of increasing survival of firms (Grandi & Grimaldi, 2005).

2.4.2.4.2.2 Science (Technology) parks

Technology parks provide environments where Small to Medium Enterprises flourish (Lin & Tzeng, 2009). These technology parks are usually created by governments which set aside regions that are designated as technology zones. Special incentives are provided to companies willing to relocate to these zones. Government also make it fairly simple for a new business to obtain necessary legal documents, facilities, and telecommunications needs (e.g., phone and internet connections) (Hu, 2007).

2.4.2.4.2.3 Convergence Centres

Along the same lines are convergence centres proposed by Mclaughlin Rotman Centre for Global health in Toronto (Kamunyori et al., 2008). In these centres, it is envisaged
that there will be a shared space in one building that will be composed of a physical centre, a virtual network and a product development fund. These centres serve to link the various actors in an innovation system together as well as provide shared scientific infrastructure that can be utilized by different groups. The main objective of these centers is to provide a one stop shop for health technologies in developing countries. A similar organization exists in Toronto, where the MaRs innovation centre puts under one roof, many players in the innovation chain in Ontario, Canada. I will explain more details about convergence innovation in the results section as well as my role in developing this center in Rwanda.
2.5 Innovation in sub-Saharan Africa

This section features a review of empirical literature on science based health innovation and biotechnology in sub-Saharan Africa. The objective of this section is to situate the study in the socio-economic context. The section begins by discussing how the innovation systems in sub-Saharan Africa are a reflection of the overall economic state in Africa before looking at features of the various components that make up the innovation system.

2.5.1 Sub-Saharan Africa: An overview

Sub-Saharan Africa is home to approximately 1 billion people living in 46 countries (see Figure 1). Although historically, the region has had the slowest growth rate globally, this begun to change during the last two decades, with many countries registering positive economic growth rates that exceed the world average (IMF, 2010). African economies have continued to sustain the growth momentum of the 1990s, recording an overall real GDP growth rate of 5.8 percent in 2007 with more than 30 sub-Saharan African countries recording higher economic growth rates in 2007 compared to 2006 (World Economic Forum., WorldBank., & African Development Bank., 2009). As a result of this improved economic growth rate, African countries have managed to reduce poverty significantly in recent years, halting and reversing the pathetic situation of the 1980’s (Porter & Schwab, 2008).

Figure 1: Map of SSA showing countries that were studied
2.5.2 Innovation systems in sub-Saharan Africa

A number of studies have been done on the NIS of most African countries but it is only South Africa that has had its NIS reviewed by OECD (OECD, 2007). The innovation systems in most countries in sub-Saharan Africa are a reflection of the overall economic environment. Most are poorly organized and highly fragmented (Oyelaran-Oyeyinka & McCormick, 2007). Industrial performance is undermined by low competitiveness and deficiencies in science and technological infrastructure (Lall & Pietrobelli, 2005; World Economic Forum. et al., 2009). The private sector is characterized by a large number of micro-enterprises operating in the informal economy while public-sector institutions are also engaged in business activities, including the promotion of enterprise development, export, and foreign investment. There are also few foreign owned firms which in most cases are not aligned with the country’s economy.

The innovative capacity of most countries in sub-Saharan Africa still lags behind the rest of the world, with only South Africa and Mauritius ranking competitively in global innovation (World Economic Forum., 2010). The majority of African countries lack research capabilities in diseases that affect their countries, lack administrative and resource capacities to negotiate in international fora, and lack production capacity in modern pharmaceutical industry.
A few case studies have looked at innovation systems in some countries in Africa. Oyelaran-Oyeyinka and Padmashree (2007) surveyed literature and policy documents on innovation systems of Kenya, Uganda and Tanzania (Oyelaran-Oyeyinka & Sampath, 2007b). These case studies looked at institutions involved in innovation in these countries as well as the innovation process. The major conclusion from this survey was that there was low technology innovation taking place in these countries; informal information flows facilitated knowledge transfer but that there were broken linkages in the innovation chain that prohibit the proper functioning of the innovation systems.

Al-Bader et al (2009) undertook an ethnographic case study of health biotechnology innovation of South Africa (Al-Bader, Frew, Essajee, Liu, Daar, & Singer, 2009). This study identified several companies that produce vaccines, antibodies and diagnostics for local and global markets. Despite this however, the study identified challenges that the health biotechnology sector in South Africa faces which include a shortage of both relevant skilled scientists and capital, primarily venture capital; poor business environment for SME’s including exchange controls that make it difficult to secure outside investment, difficulties in obtaining work permits for foreign scientists, slow regulatory approval times for clinical trials and procurement policies that undermining domestic innovation.

2.5.2.1 Elements of the Science based Health innovation and biotechnology system in Africa

2.5.2.1.1 Policy setting

Weaknesses in policy setting in Africa have been cited as one of the major drawbacks to science based health innovation in Africa (Juma & Serageldin, 2007). Nonetheless, several attempts have been made to come up with a uniform STI policy setting for African countries, though individual countries have their own policies. For example, the 8th African Union Summit was devoted to the theme “Science, Technology and
Scientific Research for Development’. Nonetheless, policy setting still remains within the mandate of different African governments.

In most African countries there is no formal national health innovation policy or R & D priority setting processes but instead these are embedded within the countries STI policies (Oyelaran-Oyeyinka & Sampath, 2007a). Mugabe (2009) reviewed science and technology policies in several African countries and suggested that only few of the countries have general frameworks that include health in the broad priority areas of R & D. For example, Rwanda, Kenya and Tanzania’s strategy for Science, Technology and Innovation outlines health, energy, mineral resources, agriculture, construction, and marine sciences and fishing as the country strategic R & D areas. In a few of the countries, health innovation policies are embedded within the national science and technology policy. Government priorities of health R & D seem to emerge from political statements. For most countries, R & D priorities are often set by or at the level of individual research institutions based on the institutions’ anticipation of funding from national governments or international donors. R & D priorities are also set within sectors such as agriculture and health, and at the level of individual departments or ministries (Mugabe, 2009).

Ministries of Science and Technology have also been set up in many African countries and act to highlight the role of science and technology at the political level. In his review, Mugabe (2009) notes that the framework through which health R & D is often carried out in Africa is usually guided by legislative documents that promote science and technology in general e.g. Kenya has Science and Technology Act of 1977 (amended in 1980), plans and strategies e.g. Botswana’s National Research, Science and Technology Plan (2005) and Mozambique’s Science, Technology and Innovation Strategy (2006): 10 Years Horizon, and in white papers e.g. South Africa’s Science and Technology White Paper of 1996. Some countries have multiple policy framework documents. For example, in

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17 The Addis Ababa Declaration on Science and Technology and Scientific Research for Development adopted by Heads of State and Government of the African Union, Ethiopia, January 2007 can be found at
addition to the National Research, Science and Technology, Botswana has the Science and Technology Policy (1998) while South Africa has the National Research and Development Strategy (2002), and the Ten-Year Innovation Plan (2007) in addition to the white paper (Chataway et al., 2009).

There have been efforts to set R & D priorities in health biotechnology in Ghana, Kenya, Namibia, South Africa, Uganda, Tanzania, and Zimbabwe in the past five years or so ((Al-Tuwaijri et al., 2004; Chataway et al., 2009). This has been done through legislation of national biotechnology policies that provide the policy framework that guides R & D in health biotechnology.

There have been a number of high level policy initiatives that have been initiated in Africa with declarations to increase funding for R & D. For example in 2007, African Union Heads of State committed to devoting 1% of their GDP to science and technology. However these commitments have rarely been met\(^\text{18}\).

2.5.2.1.2 Science based Health Research and development in Africa.

Oyelaran-Oyeyinka and McCormick (2007) stated that health R & D activities in sub-Saharan Africa are very low and are dominated by public-sector research institutions (Oyelaran-Oyeyinka & McCormick, 2007). In addition, the author’s suggests that universities and other institutions of higher learning are also involved in health R & D in addition to their core business of education and training. According to the author, current investments in R & D are largely focused on research projects of short-term nature with a limited focus on building and/or improving infrastructure for R & D. As a result R & D institutions (especially laboratories) of most African countries are of low quality when compared to those of middle-income countries and the rest of the world.

Several regional and national reviews of research institutions in Africa have been carried out\textsuperscript{19,20}. These studies show that some countries, for example Kenya, have research institutes dedicated to health while in others health research is concentrated among departments of the ministry of health and academic institutions e.g. Uganda (ANSTI, 2005). They also suggest that the highest concentration of large health related R & D research institutions and R & D-performing universities are in South Africa followed by Nigeria, Kenya and Ghana (Mugabe, 2009).

South Africa has seven large science councils with numerous research institutes and 22 public universities of which five are dedicated to scientific research and technology (Al-Tuwaijri et al., 2004). The country also has specialized national laboratories or facilities that are managed by the National Research Foundation. Kenya hosts the laboratories of several international research organizations, among them the International Centre for Insect Physiology and Ecology (ICIPE) as well as several regional research programmes.

The quality of the research institutions differs greatly with those in South Africa being relatively well endowed with laboratory equipment that is comparable to most developed countries. This is followed by research institutions in Kenya (World Economic Forum. et al., 2009). Nonetheless, in general, the review of the state of R & D infrastructure in African institutions of science and technology training, mainly universities, by the African Network of Scientific and Technological Institutions (ANSTI) concluded that most research institutions lack high quality equipment and also rely on old equipment (ANSTI, 2005).

In addition, authors continue to decry the disproportionate match between research productivity in Africa and the local disease burden. While 25% of global burden

\textsuperscript{19} SARUA (2008), \textit{A Baseline Study on Science and Technology and Higher Education in the SADC Region}. Southern African Regional Universities Association, Johannesburg.

measured in DALYs (Disability-adjusted life year’s) is in Africa, (ANDI, 2009) the most productive African countries in terms of biomedical research publications, such as South Africa, Egypt and Nigeria, generate 15 to 150 times less research articles than leading developed countries and 1.2 to 8 times less than other developing countries like Argentina, Brazil, India, or Thailand (ANDI, 2009).

A report by ANDI, (2009) also showed that there are still major challenges, which prevent research efforts to reach the scale and productivity they should (ANDI, 2009). Some of the challenges identified in the report are:

a) Significant research gap for diseases disproportionally affecting Africa
b) Low Industry-research collaboration in Africa.
c) Insufficient investment and ownership of R&D in and for Africa.
d) Institutional weaknesses
e) Low scientific capacity

The ANDI report shows that linkages between research institutes and the private sector have not taken place in most African countries and suggests that this could be because neither side truly appreciates the value that the other partner can offer. The report continues to suggest that at the same time, industry often complains that there is lack of trust from academia with their technologies and as such they would rather sit on ideas than share them with entrepreneurs. On the other hand, academic institutions do not want to have their research agenda driven by entrepreneurs as they derive most of their funding from the government and donors.

The relevance of existing research and training institutes in Africa has been questioned for their lack of linkages with the productive sectors and their limited ties to dominant actors in the economy such as SMEs (Oyelaran-Oyeyinka, 2006). This gives rise to the poor coordination of knowledge and economic production functions, and leads to imbalances in the demand and supply for skills of the right kinds, quantity, and quality
mix at sectoral levels and over time. Oyelaran-Oyeyinka (2007) described the knowledge sector as “operating in an ivory tower” and a “university system poorly connected to local realities” (Oyelaran-Oyeyinka, B. 2007).

According to many authors, the bulk of R & D in Africa is supported by the government and foreign donors with little private sector participation. The research community is limited to a few public universities and national research institutes, which is usually not connected to the local needs and opportunities (Lall & Pietrobelli, 2005; Oyelaran-Oyeyinka & McCormick, 2007). And even in manufacturing, technological content is lacking (Lall & Pietrobelli, 2002).

Figures 2 and 3 below show the major sources of funding and major performers of R &D in Africa.

**Figure 2: Sources of R&D funding in selected African countries, 2007 or latest available year**

![Source: (UNESCO. Institute for Statistics (UIS), 2009).](image-url)
Figure 3: A breakdown of R&D investment in select countries in Africa by sector of performance, 2007 or latest available year

Source: (UNESCO. Institute for Statistics (UIS), 2009)

From figures 2 and 3, it shows that in Africa, the business sector plays a very small part in R & D, with government being the most important funding sector and government and higher education institutions being the most important performers. In general R & D in universities is severely under-funded\(^{21}\). Projections by ANDI suggest that USD 14 billion is required yearly in order to close the R & D gap with the world median (ANDI, 2009).

Technological support services and infrastructure (e.g., metrology, quality control, and standards) are relatively poor and links with technology institutions are confined to necessary, rather basic activities, like mandatory certification of products or materials testing (Lall & Pietrobelli, 2002; Morel et al., 2005).

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There is no institutional base in most health research institutes for innovation and many of them lack human capacity (Oyelaran-Oyeyinka, 2006). The main work is research, teaching, consultancy, and testing and laboratory services. A few of them engage in contract manufacturing.

Research capacity is composed of the institutional and regulatory frameworks, infrastructure, funds, and sufficiently skilled people to conduct and publish research. This capacity differs widely across countries in sub-Saharan Africa especially with regards to the absolute number of researchers as well as specific competencies (Kilama, 2009). Some countries, for example Kenya and Nigeria rank quite well when it comes to the quality of their research institutions. Kenya’s innovative capacity is ranked an impressive 48th on the Global competitive index mainly due to its relatively high company spending on R & D and good scientific research institutions showing strong collaboration with the business sector in research activities (World Economic Forum, 2010). When scientific publications\(^{22}\) are used to measure R & D capacity, SSA in general also lags behind the rest of the world. For example, the continents total research publications are less than those from a single country like Brazil. Most of Africa’s research publications come from North Africa and South Africa.

When it comes to publication by research discipline, health sciences leads other disciplines in the number of research publications from Africa but this is still significantly less than in other regions of the world (Pouris & Pouris, 2009). Universities in SSA are weak when it comes to research, mainly due to being overburdened with undergraduate teaching. There is usually no institutional IP policy, hence no motivation for health product development. Many are poorly managed, and often lack essential research facilities, including poor internet services (Kilama, 2009).

\(^{22}\) By Scientific Publications I mean in all fields and not just those related to health sciences.
Lack of finances has also affected research output from many African countries. This has hindered acquisition of advanced scientific equipment as well as reagents that are necessary for successful R & D to occur. In Nigeria for example, a study by Oyelaran-Oyeyinka et al. (2006) found that scientists did not have enough finance to purchase such items as protein targets to conduct mechanism screens (Oyelaran-Oyeyinka, 2006). Perhaps it is because of this, Oyelaran-Oyeyinka argues, that these institutions keep losing the most talented researchers to foreign universities (brain drain). Other issues identified in this study by Oyelaran-Oyeyinka include absence of basic infrastructure including regular electricity interruptions and constant water shortages which result in specimens getting destroyed and inhibits optimal research conditions being achieved.

A number of institutions in Africa are involved in clinical trials for western pharmaceuticals. For example, KEMRI is taking part in a trial to evaluate the efficacy and safety of a gatifloxacin-containing regimen of four months duration for the treatment of pulmonary tuberculosis\(^23\). KEMRI has also been conducting clinical trials since 2003 for vaccine development by IAVI (the International AIDS Vaccine Initiative)\(^24\).

2.5.2.1.3 Health R & D financing in Africa

The ANDI report in 2009 compared expenditure on science based health innovation in Africa to the rest of the world in 2000 and found that Africa as a whole accounted for less than 1 percent of the world’s expenditure on R & D. Projections by ANDI suggest that USD 14 billion is required yearly in order to close the R & D gap with the world median (ANDI, 2009).

The bulk of science based health innovation in sub-Saharan Africa is funded by domestic governments and foreign donors. It is difficult to establish the exact amount of public financing spent on R&D in Africa as data is scanty. There are no institutions and/or

\(^{24}\) https://www.era.lib.ed.ac.uk/handle/1842/2743
programmes that keep records on R & D in general, leave alone R & D expenditure on health. However, attempts at carrying out surveys have been supported by several organizations including the United Nations Educational, Scientific and Cultural Organizations (UNESCO) Institute for Statistics (UNESCO. Institute for Statistics (UIS), 2009) and NEPAD but the results have not been published.

Mugabe (2009) states that although Africa has a number of domestic private equity companies, venture capital firms, commercial and development banks, many microfinance institutions, private foundations, and many bilateral and multilateral donors, they have not invested in health product commercialization (Mugabe, 2009).

South Africa is the only country in Africa which has a domestic private venture capital fund dedicated to health biotechnology. A similar venture capital firm, Bridgeworks E.A, was established in Kenya but sustainability issues made it fold. There is limited international venture capital invested in health product commercialization, the exception being Acumen’s Fund investment in the long-lasting mosquito net manufacturer, A-Z textile of Tanzania (Mugabe, 2009).

A number of countries have established agencies and funds aimed at supporting innovation. Examples of such agencies include; the Botswana Research, Science and Technology Investment Agency; South African Innovation Fund and the Technology and Human Resources for Industry Programme (THRIP) 25 administered by the National Research Foundation (NRF); Uganda millennium science initiative 26 and Presidents National Innovation Fund; Kenya’s National innovation fund 27 and Zimbabwe Innovation Commercialization Fund 28. Ghana and Kenya have established endowment funds for scientific research and technological innovation. However, none of these funds is dedicated specifically to investments in science based health product commercialization.

25 http://thrip.nrf.ac.za/about.html
28 http://www.rcz.ac.zw/
2.5.2.1.4 Intellectual Property in Africa

There is generally low level of interest regarding IP in most African countries despite the fact that most countries laws on intellectual property protection and institutions to administer the laws (Phillips, 2008). In many of the countries patent information is rarely searched and used by researchers. Less than one thousand patents filed globally had addresses from Africa, indicative of the continent’s low inventive profile (Pouris & Pouris, 2009). Furthermore, patent applications came from only a few countries with 88% from South Africa, with Kenya being the next with about 2 %. Only Kenya, Mauritius, and South Africa have relatively well staffed and equipped independent industrial property offices or organizations. In most other countries, intellectual property laws are administered by ministries of trade and industry and thus are weak, understaffed and underequipped.

African countries are also parties to international treaties such as the Paris Convention (industrial property) and the World Intellectual Property Organization (WIPO) Convention. English-speaking African countries are also members of the African Regional Intellectual Property Organization (ARIPO) whose headquarters is located in Harare, Zimbabwe. ARIPO was established to enable these countries pool the resources industrial property matters to avoid duplication of financial and human resources.

One clearly discernable feature is the big difference between research publications and patenting. Few researchers have been able to patent their work. This could be attributed to lack of knowledge on IP issues, lack of support by donors, who are the primary funders of research and the high cost of patenting especially in the US and Europe (Pouris & Pouris, 2009).

2.5.2.1.5 Regulatory capacity in Africa

Regulation, which is fundamental to successful health innovation, poses a great challenge to African countries. Most African countries have drug regulatory agencies which have been enacted by legislation but competencies differ between the countries (Burki, 2010). A 2010 WHO report found that about 90% of the medical regulatory authorities (MRAs) in the African region were not able to guarantee the quality, efficacy, and safety of medicines (The George Institute for International Health, 2010). Table 1 below illustrates the diversity of drug regulation agencies in Africa from data published by WHO.

Table 1: Features of drug regulatory agencies in Africa

<table>
<thead>
<tr>
<th>Key features</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory framework</td>
<td>Most African countries had agencies established by legislation</td>
</tr>
<tr>
<td>Regulatory scope</td>
<td>In addition to regulating human medicines, 65% of MRA’s controlled veterinary drugs, 69% traditional or herbal medicines, 42% other products including foods, poisons, pesticides, bottled water, cosmetics, 42% were involved in designing and implementing national medicines strategies and public medicine supply.</td>
</tr>
<tr>
<td>Organizational form</td>
<td>26% were departments in the Ministry of Health, with no autonomy to manage their own funds or human resources</td>
</tr>
<tr>
<td>Regulatory functions</td>
<td>15% carried out marketing authorization, licensing, inspection, quality control and pharmacovigilance under one roof; 65% had access to a functional national regulatory quality control laboratory</td>
</tr>
<tr>
<td>Structure and management</td>
<td>Most depend on fees paid for services; 34% depended entirely on government funding</td>
</tr>
<tr>
<td>Medicines Registration</td>
<td>73% carried out some evaluation of technical documents to a varying degree of stringency but were generally not in line with WHO standards; the capacity to assess applications for new innovator products is almost nonexistent.</td>
</tr>
<tr>
<td>Legal basis and regulation</td>
<td>69% operated within a legal basis which empowered them to assess applications for market authorizations; 17% had provisions which exempted a wide range of products (such as donations) from registration irrespective of risk.</td>
</tr>
<tr>
<td>Guidelines</td>
<td>Only 12% of the countries had guidelines describing the required content of submissions (but not in line with WHO guidelines)</td>
</tr>
<tr>
<td>Expert assessors</td>
<td>92% of the countries reported shortage of adequately qualified assessors in specific technical areas</td>
</tr>
<tr>
<td>Quality control</td>
<td>Only 19% had a functioning regulatory laboratory for quality control; 54% lacked a quality monitoring program.</td>
</tr>
<tr>
<td>Clinical trials</td>
<td>In 69% of the countries, clinical trials were controlled to some extent</td>
</tr>
</tbody>
</table>
The above table shows that many drug regulatory agencies in Africa have little autonomy, suffer from shortage of sustainable funding, political motivation is scant, and qualified staff hard to come by and thus are unable to oversee the full range of regulatory functions.

For existing products, these agencies have for the most part relied on approving products already approved by other agencies notably the US Food and Drug Administration (FDA) and the European Medicines Agency (EMEA). However, the biggest challenge is the evaluation of the safety, efficacy and quality of new medicines\(^33\) (The George Institute for International Health, 2010).

2.5.2.1.6 Markets

Both the public and private sector play a key role in the health care market in Africa. According to WHO estimates, the total health expenditure in Africa in 2007 was US $16.7 billion\(^34\), out of which around 60 percent, was financed by private parties with the rest coming from governments and donors. The IFC estimates that based on projected economic and population growth rates, the health care expenditure in Sub-Saharan Africa is expected to grow to $35 billion in 2016\(^35\). WHO also estimates that in most African countries, out-of-pocket expenses account for over 90 % of the private sector expenditure on health. The remainder of the private sector funding comes from nongovernmental providers (Bloom, Canning, & Jamison, 2004).

However, purchasing power in Africa is low with only 1% of total spending on global pharmaceuticals occurring in Africa (Scheffler & Pathania, 2005). Prices of drugs in Africa are also relatively low compared to the US and European markets and this has been mainly due to importation of generic medicines from India. The medical supplies market is estimated to be US $2.1 billion with most of it composed of imported products\textsuperscript{36}. Because of the low purchasing power, when faced with a choice between various interventions e.g. for preventing malaria, most patients will choose the cheapest choice regardless of quality.

The private vaccine market in Africa is small. In most cases, vaccine provision is the duty of governments as most of the population cannot afford vaccines e.g. in Nigeria only 0.03% privately purchases US $12 Hep B vaccines.\textsuperscript{37}

2.5.2.2 Products developed in Africa

There are a wide range of health products being developed in African countries. The most common health products being developed are drugs from traditional plant medicines. There are very few medical devices, vaccines and diagnostics being developed.

2.5.2.2.1 Traditional plant medicines in Africa

The World Health Organization (WHO) estimates that up to 80% of Africans rely on traditional plant medicine as their primary source of medication (WHO, 2002). Some African phytomedicines, like Hoodia from South Africa, are well known in the international market resulting in economic benefits for the producing countries. There are many studies in almost all countries in Africa that have documented traditional plants of

\textsuperscript{36} IFC Health In Africa 2007: The Business of Health in Africa  

\textsuperscript{37} The Boston Consultative Group, February, 2005. Market assessment for malaria vaccines
medicinal value that are available. A few examples include Kokwaro (1976), Okigbo and Mmeka (2006) and Sofowara (1982) (Kokwaro, 1976; Okigbo & Mmeka, 2006; Sofowora, 1982).

Okigbo and Mmeka (2006) found that the main illnesses targeted by African herbal medicine are identified as: Malaria, infectious gastroenteritis, diarrhea, dysentery, diabetes, measles, meningitis, tuberculosis, HIV, pneumonia, smallpox, gonorrhea, tropical ulcers, Schistosomiasis, filariasis, onchocerciasis, Trypanosomiasis, worms (especially Guinea worm), tachycardia, fibroids, palpitation, back pain, and snake-bites (see table 2) (Okigbo & Mmeka, 2006). These are illustrated in table 2 below.

**Table 2: African medicinal plants with their medicinal value**

<table>
<thead>
<tr>
<th>Plants</th>
<th>Disease Cured</th>
<th>Action</th>
<th>Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Xylopia aethiopica</em></td>
<td>intestinal spasms, cough, post partum tonic, for lactation, stomach remedy, bronchitis, biliousness, dysentery, headache, female hygiene</td>
<td>Soothing, antispasmodic, remove biliousness, emollient, sedative</td>
<td>poultice of the plant</td>
</tr>
<tr>
<td><em>Garcinia kola</em></td>
<td>bronchitis, throat infections, relieve colic, head or chest cold, cough, liver disorder</td>
<td>Antibiotic, antispasmodic, soothing, sedative, ease cough, expectorant, choleretic</td>
<td>eating the seed of the plant</td>
</tr>
<tr>
<td><em>Vitex doniana</em></td>
<td>gastroenteritis, diarrhoea, dysentery, infertility, eye diseases</td>
<td>Antimicrobial, invigorating and anti-inflammatory</td>
<td>stem bark decoction</td>
</tr>
<tr>
<td><em>Crysolepis sanguinolenta</em></td>
<td>fever, malaria, urinary and upper respiratory tract infection, rheumatism, venereal diseases</td>
<td>antiplasmodial, antiviral, antispasmodic, expectorant, anti-inflammatory</td>
<td>hot poultice of dried root</td>
</tr>
<tr>
<td><em>Euphorbia hirta</em></td>
<td>bronchial and respiratory disorders, urinary disorder, skin diseases, ocular diseases and dysentery</td>
<td>Soothing antispasmodic, regenerates skin, emollient antiparasite, anti-inflammatory, anti-inflammatory, antimitotic, antiviral, antibiotic, diuretic</td>
<td>Aqueous decoctions of the plant, latex of the plant for cuts and warts</td>
</tr>
<tr>
<td><em>Ocimum gratissimum</em></td>
<td>Respiratory infections, diarrhoea, headache, ophthalmic (ocular) diseases, skin diseases, pneumonia, cough, fever, conjunctivitis</td>
<td>Anti-inflammatorv, soothing, expectorant, invigorating, antiseptic, sedative, emollient</td>
<td>aqueous and ethanol extracts of the leaves</td>
</tr>
</tbody>
</table>
Citrus aurantifolia nervousness, anxiety, insomnia, gastroenteritis

Sedative, mildly narcotic anti-inflammatory

infusion of leaves and flowers (orange blossom) ethanol and aqueous leaf extracts

Cajanus cajan

sickle-cell anaemia

Anti-anaemic because of phenylalanine

seed

Source: (Okigbo & Mmeka, 2006)

In addition, there are a number of African phyto-medicines in the international markets as shown in Table 3 below.

Table 3: Some African phyto-medicinals in the world market

<table>
<thead>
<tr>
<th>Plant species</th>
<th>Action</th>
<th>Constituents</th>
<th>Source countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ancistrocladus abbreviatus</td>
<td>Anti-HIV</td>
<td>Michellamine B</td>
<td>Cameroon and Ghana</td>
</tr>
<tr>
<td>Corynanthe pachyceras</td>
<td>Male stimulant</td>
<td>Corynanthidine, corynanthine, yohimbine</td>
<td>Ghana</td>
</tr>
<tr>
<td>Tamarindus indica</td>
<td>Insecticides</td>
<td>Pectins</td>
<td>Egypt</td>
</tr>
<tr>
<td>Rauvolfia vomitoria</td>
<td>Tranquilizer and antihypertensive</td>
<td>Reserpine, yohimbine</td>
<td>Nigeria, Zaire, Rwanda, Mozambique,</td>
</tr>
<tr>
<td>Cinchona succirubra</td>
<td>Anti malarial</td>
<td>Quinine</td>
<td>West African countries</td>
</tr>
<tr>
<td>Syzgium aromaticum</td>
<td>Dental remedy</td>
<td>Eugenol, terpenoids</td>
<td>East Africa countries, Madagascar</td>
</tr>
<tr>
<td>Agava sisalana</td>
<td>Corticosteroids and oral contraceptives</td>
<td>Hecogenin</td>
<td>Tanzania</td>
</tr>
<tr>
<td>Physostigma venenosum</td>
<td>Ophthalmia</td>
<td>Physostigimine (eserine)</td>
<td>Calabar (Nigeria), Ghana,Cote D'ivoire</td>
</tr>
<tr>
<td>Prunus africana</td>
<td>Prostate gland hypertrophy</td>
<td>Sterols, triterpenes, n-docosanol</td>
<td>Cameroonian, Kenya, Madagascar</td>
</tr>
<tr>
<td>Catharanthus roseus</td>
<td>Spice, carminative and medicinal products</td>
<td>Gingerol</td>
<td>Nigeria</td>
</tr>
</tbody>
</table>
Chrysanthemum cinerariifolium | Insecticides | Pyrethrins | Ghana, Kenya, Rwanda, Tanzania, South Africa

Source: (Okigbo & Mmeka, 2006)

Okigbo (2006) notes that public interest in phytomedicines has been increasing globally partly because of the belief that phytomedicines are devoid of side effects because these products have been used historically by millions of people all over the world (Okigbo & Mmeka, 2006). This author further suggests that whenever conventional treatments for certain diseases fail, or does not exist, patients resort to phytomedicine.

Because of Africa’s rich biodiversity there has been increased focus on the potential of traditional medicine to alleviate some of the health challenges that Africa faces. In Africa, almost all universities and the national public research organizations now have departments that are involved in one way or another researching into the use of traditional knowledge (Mytelka, 2006; Sampath & Oyelaran-Oyeyinka, 2007).

Most of the university research is centered around biopharmacy and on evaluation of toxicity of plants and safety as well as validation of the remedies. In some countries there are institutions that are set up specifically for biopharmacy research, with notable examples being the National Institute for Pharmaceutical Research and Development (NIPRD), in Abuja, Nigeria and Centre for Scientific Research into Plant Medicine in Mampong, Ghana. In Nigeria, research on a traditional plant remedy led to the development of a drug, Nicosan, for the management of sickle cell anemia (Nathan, Tripathi, Wu, & Belanger, 2009).

There are many firms emerging in Africa that deal with herbal preparations made using traditional medicinal knowledge, but most are limited to sales of whole plant extracts with little value addition.
2.5.2.2 Pharmaceuticals

The IFC has estimated that the pharmaceutical market in SSA is worth about $3.8 billion (IFC, 2007). This is mostly consisting of generic manufacturing as, outside South Africa, there is hardly any private sector pharmaceutical R & D in SSA. About US $1 billion or 25-30% of this value was developed by locally based pharmaceuticals with South Africa controlling about 70% of the annual production, and Nigeria, Kenya, and Ghana, controlling around 20% with the other African countries sharing the remainder. Although 37 other countries have some type of pharmaceutical production, they account for only 10% of pharmaceutical manufacturing. Only South Africa and Kenya export pharmaceuticals, with 35-40% of Kenya’s manufacturing sales going to regional export. A drugs producer in Uganda became the first in a least developed country (LDC) to achieve a world-class seal of quality for its manufacturing standards. There are around 37 pharmaceutical manufacturers in sub-Saharan Africa (Anderson, 2010).

In terms of distribution, there is a diverse distribution chain, including various types of unauthorized outlets i.e. non-registered pharmacists, indicative of an informal market (The George Institute for International Health, 2010).

An IFC report, *Business of Health in Africa* (2007), states that most of the manufacturers outside South Africa manufacture non-complex compounds (IFC, 2007). According to this report, manufacturing in Africa mainly constitutes simple activities like packaging medicines, repacking formulated drugs and processing bulk drugs into doses using predominantly imported active ingredients and excipients. The bulk of locally manufactured preparations are non-sterile, over-the-counter (OTC) products such as basic analgesics, simple antibiotics, anti-malarial drugs, and vitamins.

The report attributes this to the following factors: SSA manufacturers generally produce at a cost disadvantage to the large Asian generic manufacturers due to the scale of production; production cost disadvantage including a more expensive asset base often
coupled with obsolete technology, financing costs and lack of integration with Active Pharmaceutical Ingredients (API) production; import difficulties and the fragmentation of distribution networks that make shipping to other markets in SSA more expensive than Asia-to-Africa shipping; intra-African imports being subjected to the same import tariffs as intercontinental ones.

Other areas of manufacturing include industrial manufacturing of herbal products based on traditional medicinal knowledge. This comprises a broad range of products, such as herbal antibiotics, hygiene products for women, products for reproductive illnesses and general system cleansers.

Two new mechanisms have been put in place to encourage local pharmaceutical manufacturing in Africa— the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and the African Union Pharmaceutical Manufacturing Plan (Berger et al., 2009).

2.5.2.2.3 Medical devices and diagnostics

According to the IFC report mentioned in the preceding section, sub-Saharan Africa’s medical supplies market is estimated to be $2.1 billion with most of it composed of imported products. Medical devices manufactured locally represent products of low manufacturing complexity using locally available raw materials like cotton and plastic material. The report states that medical devices that are currently produced in SSA include disposable syringes, surgical gauzes and padding material. Other devices include mosquito nets—especially the long-lasting insecticide treated mosquito nets (LLINs)—with the most notable manufacturer being A-Z textile manufacturer in Arusha, Tanzania.

According to the IFC report, the reason why Africa still manufactures only low technology medical devices is that manufacture of medical devices is complex and highly specialized and Africa lacks the scientific infrastructure as well as human resource
capacity. In addition, the report states that lack of local manufacturing can be attributed to the small scale of production, small markets, and the established expertise or proximity to raw materials (such as latex) of other production sites.

The IFC report has categorized products manufactured in Africa to fall into four broad categories:

a) Bulky products such as hospital furniture

b) Products that make use of locally available raw materials. It is easy to develop vertically integrated industries due to lack of tariffs on local raw materials making it viable to produce goods such as gauzes and dressings. For example, cotton is grown in Uganda, Senegal, and Mozambique, and manufacturing finished cotton products would be easy.

c) Products that require customization. Items such as prosthetics and eyeglasses typically require proximity to users.

d) High-value products and products in high tariff categories. For example, Disa Vascular in South Africa can supply the local market with high-quality coronary stents, relying not only on state-of-the-art technology but also on its protection from import duties.

2.6 **Synthesis of the literature review**

This chapter has broadly explored the literature for this thesis from four broad areas; the theoretical innovations literature; innovation in developing countries; science based health innovation; and literature on innovation in Africa. The chapter has laid out the theoretical argument using the wider innovations literature as well as provided available empirical literature on health product commercialization in Africa. It has also defined key concepts and discussed the framework that shapes analysis of innovation; including describing its various features.
As this chapter has shown, there is abundance of literature on many aspects of innovation including its definition and application. Several scholars have emphasized the importance of innovation systems as a framework for innovation (Freeman & Soete, 2007; Lundvall, 2010; Oyelaran-Oyeyinka, 2006). These systems are usually bounded by boundaries. Determining which system to use in analyzing innovation depends on the analytical and methodological issues at hand.

The literature review has also shown areas of divergence of discussions on innovation in developed and developing worlds. For example, several international organizations including the Organisation for Economic Cooperation and Development (OECD), World Bank, World economic forum recommend the use the NSI concept for analyzing innovation (Lundvall, 2010). But other authors, notably Erbil, (2007), Mani (2004), Dantas (2005), Ahrens (2005), Lall & Pietrobelli (2003) etc have also questioned the applicability of the NIS in developing countries (Ahrens, 2005; Dantas, 2005; Erbil, 2007; Lall & Pietrobelli, 2003; Mani & Romijn, 2004) suggesting that because external factors affect a government’s ability to execute autonomous policies, national innovation system cannot be applied as in developed countries.

Further divergence in the literature is in the definition of the term innovation as it applies to developing countries. While innovation has been described as “the implementation of a new or significantly improved (novel) product (good or service), or process”, this definition is applicable mainly to the developed world (OECD, 2005). In contrast, the literature describes authors who have defined innovation in the developing world as “local improvements of technologies developed elsewhere; modifying imported technologies to suit local conditions (usually focused on cost reduction); or less commonly, novel product development (Aubert, 2005; Edquist, 2005; Frew, Kettler, & Singer, 2008). These divergent views by authors have been attributed to various factors including difference in focus and national origin of the author (Johnson et al., 2003).
Despite the divergence, however, there are also areas where there is agreement in the literature by authors concerning innovation literature of the developed world and of developing world. Among these areas is that regardless of setting, innovation is enabled by the interaction of various actors (Holbrook & Hughes, 2003). These actors, who include government policy makers, academic and research institutes, the private sector, the market produce various elements that affect innovation and these include intellectual property, innovation environment and regulatory policies.

The literature review also notes that science based health innovation can be very costly compared to other forms of innovation. This, the literature reveals, is mainly as a result of three factors; the length of time science based health innovation takes, the high cost of patent protection and the need to overcome many regulatory barriers because of its use in humans (Chataway et al., 2009). There is a great deal of discrepancies between country medical regulatory authorities and the situation is even more critical in sub-Saharan Africa. However the literature does not have studies that how the true impact of these discrepancies.

The review of the literature reveals various product commercialization strategies that institutions and firms can adopt to enable their products reach markets. Among commonly applied strategies is the open innovation model (Chesbrough, 2003; Won, 2004). This model assumes that an organization can and should use external ideas as well as internal ideas, and external as well as internal paths to innovation and market – all while trying to advance its technology. If an organization lacks internal product development capabilities, then it can leverage external resources through a combination of strategies. Conversely, an organization can maximize use of its internal production capabilities by attracting innovations and ideas that have been developed outside the organization, and fully developing them.

Other commercialization strategies that the literature identified include the development of science parks, business incubators and convergence centres. Various authors reviewed
have discussed the critical contribution that these make especially in the earlier stages of product development.

The final section of the literature review looks at available empirical literature on health innovation in Africa including case studies on innovation in Africa (Al-Bader, Frew, Essajee, Liu, Daar, & Singer, 2009; Oyelaran-Oyeyinka & Sampath, 2007a). From analysis of this literature it is evident that there are systemic weaknesses in institutions that are involved in science based health innovation in Africa.

Summarized, this chapter has identified several empirical voids concerning health product commercialization in sub-Saharan Africa. There is limited literature on this topic on Africa. Although there are few country case studies (Oyelaran-Oyeyinka & Sampath, 2007a), these involved analysis of the entire innovation system with little emphasis on health innovation. In addition these case studies are limited by methodological weaknesses, as they relied mainly on literature and document survey, obscuring the implication of research results to other settings. Apart from Al-Bader’s South African study there are no in depth country case studies that rely on ethnographic data collected first hand that analyze intra institutional commercialization dynamics and how institutions interact within innovation systems in African countries. Additionally, the role and strategies of African research institutions in health product commercialization has not been investigated. Finally, while studies have shown there is some manufacturing capacity in Africa, there are no systematic studies that identify potential health technologies as well as the barriers to commercializing them. It is these gaps that this thesis seeks to fill.
Chapter Three: METHODOLOGY

3.1 Introduction

This chapter discusses the theoretical framework and the research design used in this study. The rationale behind selection of the qualitative case study research design is outlined. The chapter then discusses the collection and the analysis of primary and secondary data including the fieldwork undertaken. Also included in this chapter is an analysis of the issues surrounding the validity of the study findings as well as the limitations of the study methodology, with strategies used to overcome them. Finally the chapter addresses the ethical protocols of the study and dissemination strategies of the study findings.

3.2 Theoretical framework

In analyzing science based health innovation and biotechnology in SSA, this thesis draws primarily from innovation systems literature. Several international organizations including the Organisation for Economic Cooperation and Development (OECD), World Bank, World economic forum etc recommend the use the NIS concept for analyzing innovation (Lundvall, 2010). Chataway (2009) modified this and used the definition of system of science based health innovation to analyze health innovation in Africa. Essentially such a system is composed of actors, institutions, organizations and policies that together support innovation in health and biotechnology, along with the infrastructure and financing mechanisms that enable these systems (Chataway et al., 2009). While the characteristics of these science based health innovation systems may differ between (and even within) countries, they are bound by national borders hence the NIS framework.
The UN Conference on Technology and Development (UNCTAD) also emphasized the usefulness of the NIS in studying innovation in developing countries by recognizing that innovation is an interactive process of between many actors (Holbrook & Hughes, 2003).

3.3 Research design

3.3.1 Why case study

The present research study used an ethnographic qualitative case study research design. Case study is defined as ‘studying a contemporary phenomenon within its real-life context, and where the boundaries between phenomenon and the context are not clearly evident (Yin, 2008). Case studies are also the preferred research strategy when researching a topic on which very little is known (Bengtsson et al., 1997). It follows that sometimes by looking carefully at practical, real-life instances, a full picture can be obtained of the actual interaction of variables or events. The case study allows the investigator to concentrate on details, identify interactive processes that may be crucial yet transparent in a large scale survey and provides a three-dimensional picture of the situation. Yin, (2008) suggests that case study design must have five components; the research question(s), its propositions, its unit(s) of analysis, a determination of how the data are linked to the propositions, and criteria to interpret the findings (Yin, 2008).

I conducted three different independent studies in Africa.

Study 1: Level of analysis was at National level and the case was Rwanda.
Study 2: Level of analysis was at institutional level and the case was the Kenya Medical Research Institute (KEMRI).
Study 3: Level of analysis was at technology level and individual technologies formed the cases.
This study is an empirical inquiry into a contemporary phenomenon (science based health product innovation in SSA) within its real-life context. Very little is known about this topic in Africa, hence necessitating the need for a case study approach. In addition, historical, political and cultural contexts in which the cases are situated present many variables that affect health product commercialization. A number of similar studies reviewed adopted the case study approach, for example, studies such as those; on national health biotechnology innovation systems (Chataway et al., 2007; Cozzens, Bortagaray, Gatchair, Thakur, & Deliverable, 2008; Singer, Salamanca-Buentello, & Daar, 2005); on African health product companies and health institutions (Manveen, Hassan, Jennifer, & Peter, 2010) as well as; on health product commercialization (Manveen et al., 2010; Murphy, Dingwall, & Greatbatch, 1998; WP4 policy paper, 2009).

Rather than formulating propositions, this study aimed at understanding a phenomenon which is science based health product innovation and biotechnology in sub-Saharan Africa. Hence the study presents an analysis that is more descriptive and explanatory in nature and in line with Yin’s (2008) recommendation that case studies whose dominant model of analysis is exploratory should have explanation-building and pattern-matching as the main goal (Yin, 2008).

3.3.2 Case selection

Study 1: Country case study: Rwanda

**Rationale:** I chose Rwanda for this study because it has good political leadership that has prioritized science and technology development. The government has committed itself to increasing the percentage of its gross domestic product dedicated to R & D to 1 %. The country is also relatively small and hence the complexities of studying an innovation system are easier. The actual study was undertaken at the invitation of the Minister of science and Technology who wanted a study of the country’s health and biotechnology system undertaken in order to guide and support policy implementation.
Study 2: Health Research Institution: KEMRI

**Rationale:** I chose KEMRI as a case study because as one of the premier health research institutions in Africa, it meets the criteria for appropriateness of the study as it has attempted to commercialize its research by developing production capacity. It is also part of another study that I was involved in that is analyzing product development within the private sector in Africa hence it was convenient to carry out both studies simultaneously.

Study 3: Stagnant health technologies

**Rationale:** The following was the criteria for selection of the case studies for the stagnant technologies:

- Any technology that has health applications (e.g. vaccines, diagnostics, medical devices, therapeutics, services, nutraceuticals, Health information software).
- The technology must be an original product, service or process.
- Willingness and availability of scientists to participate in interviews.

The technologies cases were chosen from research institutes and universities in six countries, namely Kenya, Nigeria, Tanzania, Ghana, Uganda and Rwanda. Kenya and Nigeria were chosen because they represent countries that could be called the top tier in science and technology in SSA with relatively well developed innovative sectors including excellent scientific research institutions and financial sectors. Kenya has the highest rate of patenting in all of SSA, outside South Africa, followed by Nigeria, sub-Saharan’s largest economy (Porter, López-Claros, Schwab, & Sala-I-Martin, 2006). Ghana, Tanzania and Uganda were chosen because they represent middle level African countries in this respect, while Rwanda was chosen as a representative of the least developed countries in both the innovative sector and scientific institutions.
3.4 Collection and analysis of primary data collection

3.4.1 Scoping exercise

For each of the three studies, study participants, organizations and institutions of interest in sub-Saharan Africa were identified through an internet search and review of policy documents available online. The institutions and organizations that I was interested in were selected based on the national system of innovation framework and had some direct connection with health (Lundvall, 2010). Such institutions included health related R & D institutions, regulatory agencies, government ministries of health and commerce, private sector health companies, venture capitalists and donors as well as NGO’s. Individuals who were working in or who had worked with these organizations were identified based on their publications, demonstrable experience and expertise in health product commercialization. In addition, policy makers were also selected as it was important to understand and demonstrate how policy formulation affects health product commercialization.

3.4.2 Participant recruitment

In all three studies, an initial pool of study participants was selected using purposeful sampling (Rubin & Babbie, 2009). These initial participants were those identified through the scoping exercise. These participants were then contacted by email and informed of the study as well as their potential to contribute to it (see appendix A, B, C for study invitation letters for the Rwanda case study, KEMRI case study and the stagnant technology study respectively). Snowball sampling was then used to recruit additional participants. Snowball sampling is a method of sampling whereby each person from the initial pool suggests other knowledgeable individuals to contribute to a study (Marshall & Rossman, 2006).
3.4.3 Interviews

The main method of primary data collection for this study was semi-structured in-depth interviews conducted in the respective institutions. Part of the objective of using interviews was to access and subsequently understand science based health innovation and biotechnology phenomenon through descriptions of it, in the participants’ own words. The study aimed at eliciting personal accounts and experiences from actors in the system which provided insights and understanding of their identities, values, perceptions, experiences and the meanings they attach to science based health innovation and biotechnology and interviews are the best way to do this (Hitchcock, Hughes, & Hughes, 2001; Wengraf, 2001).

Prior to the interviews, informed consent to participate in the interview and to be digitally and/or video recorded was obtained from each interviewee as outlined in the ethical procedure spelt out from the University of Toronto ethics approval Board. The interviews were guided by a common set of questions that were developed from a review of literature on science based health innovation and biotechnology, research institutes and health technologies. (see appendix F and G). These acted as the basic framework for examining the phenomena and the accompanying attitudes but, given the dynamic nature and different understanding of the issues being discussed, freedom to move beyond the basic set of questions was essential. While the duration of interviews and the number of questions varied from one participant to the other, the duration was usually determined by how knowledgeable the participant was on the subject, as well as their willingness to discuss issues. On average most lasted for forty five minutes. All the interviews were digitally recorded.

Field notes detailing interesting statements like specific references that would shed more light on the issue and any other observation were also recorded. Brochures and policy documents that could be useful were also collected from the people being interviewed and these were used as supporting information or in discussion and analysis of the
recorded interviews. Each interviewee was asked to suggest a person who may provide more information on the topic. This continued until the point of theoretical saturation, whereby no new information was being obtained from new interviewees.

3.4.4 Field work

3.4.4.1 Study 1: Rwanda case study

The fieldwork for the case study in Rwanda was conducted during three weeks between November, 23rd 2007 and December 12th 2007. A total of 38 people from across the science-based health innovation system were interviewed (see Appendix C).

Specifically, the interview themes revolved around identifying the main actors in the health innovation system including the role of government policy institutions, the private sector and health R & D organizations. Linkages between the various actors in the innovation chain as well as challenges and barriers to health product commercialization were also explored.

3.4.4.2 Study 2: KEMRI case study

For the KEMRI case study, a letter from KEMRI’s Board of Management was obtained to allow me to conduct interviews there. Two visits were made to the institute in Nairobi, Kenya. The first visit was in February 2008 and a second visit was in September 2008. A diverse group of individuals was selected for the interviews and included scientists, members of KEMRI’s Management staff, members of KEMRI’s IP Management team, and members of the product manufacturing facility. In addition interviewees based in other KEMRI’s centres including the one in Kisumu and in Kilifi were selected to increase the diversity of participants. The interview themes revolved around general areas of product commercialization, motivation of scientists to commercialize ideas, institutional IP policy, and funding and innovation management.
3.4.4.3 Study 3: Stagnant technology case studies

For the stagnant health technology case studies, 18 research and academic institutes were visited and 39 scientists in Ghana, Kenya, Nigeria, Rwanda, Tanzania and Uganda were interviewed (see Appendix D for details of institutions visited). The interview questions were designed to investigate what the technologies being developed were and how and why they became stagnant. The line of inquiry focused on four broad themes: identifying the technology and stage of development, clinical benefit, advantages over imported technologies and barriers to commercialization.

3.4.5 Data analysis

The interviews were transcribed verbatim. All transcribed interviews were verified for accuracy. A modified thematic approach (Martin, Singer, & Bernstein, 2003) was then used for data analysis using ATLAS.ti, a software application for qualitative data analysis (Muhr & Friese, 2004). In this modified thematic approach, I began my analysis at the textual level by open coding, which involved breaking down raw information into common groupings based on shared ideas from the study participants; that is analyzing the data to extract a set of categories and their properties (Corbin & Strauss, 2008). Throughout the coding process, memos were developed in ATLAS to keep track of all the categories, properties, hypotheses, and issues that evolved. Information from the memos was used together with the codes.

When the codes and memos increased, axial coding (Corbin & Strauss, 2008) was used to group cross-cutting or related concepts to each other and develop main categories and their sub-categories. This enabled the construction of a number of possible coding paradigms, or themes. The categories that had been developed were integrated to

38 Axial coding is defined as the process of relating codes that have similar categories or concepts to each other.
conceptualize the key findings of these studies using selective coding. These findings formed the core of the discussion in the results section of each of the studies. Finally, the ideological underpinnings of the informants’ experiences and perceptions were summed up under a code ‘lessons learned’.

Field notes were used to further support the information gathered and analyzed from the recorded interviews. Documents gathered during the fieldwork including company and organization annual reports, brochures, and research carried out by other groups on areas closely related to my research question and reports by organizations such as the World Bank and NGOs, among others, were reviewed.

3.5 Collection and analysis of secondary data

In addition to primary data, information and key documents were collected from web searches, official government documents from respective ministries, and organization and product brochures. Examples of key documents include Rwanda’s Science technology and Innovation policy document, KEMRI’s organization brochure, and individual brochures of health products that were provide by scientists. There were also other data sources that were considered including for example published statistical information on health status in Rwanda and government investment in R & D.

3.6 Reliability and Validity of the research

The importance of quality, validity, rigor and trustworthiness, in qualitative research has been discussed by many authors (Corbin & Strauss, 2008). In this study, many issues that could affect the quality of the research findings were considered: First, to ensure that the information received was an accurate description of the situation, whenever possible, the information was triangulated with other data sources which included documents and brochures, other interviewees on the same subject, my field notes and personal observations.
Secondly, regarding the methods used in this study, I was part of a wider team of researchers. Thus, the method was designed after an extensive review of literature as well as consultation with my supervisor and other team members, many of whom had a wide array of experience in qualitative research.

Thirdly, in order to ensure that the results truly reflected what the interviewees said, I did “member check” whereby I sent interviewees the descriptions of results and whenever I used specific quotations, I counter checked with the interviewee that what I was reporting was accurate and that I was not taking participant’s comments out of their original context. Finally, I documented all research activities and kept detailed records of events, interviews, field notes/observations that can be used to critically appraise the methods used in this study.

3.7 Assumptions and limitations of the study methodology

3.7.1 Assumptions

The focus of this study was to explore health product commercialization in sub-Saharan Africa. The selection of study participants was based on the assumption that the people selected to participate in the interviews were those with the most knowledge on health product commercialization in sub-Saharan. I assumed that participants in this study were honest and forthcoming. In addition, verifying truthfulness and accuracy (including those over-rating or exaggerating their claims) in the study at technology level was difficult as participants were told not to disclose non-patented potentially proprietary information.

3.7.2 Limitations

The major limitation in this type of study methodology is the tendency to generalize the research approach to other African countries and research institutions. Sometimes
obtaining permission from institutions to conduct interviews and the confidence from scientists to disclose information is not easy as some of the information is potentially patentable. This can lead to a small sample size of participants interviewed. However, the goal of qualitative research is to find enough participants that can adequately provide a full and rich description of the study focus (Creswell, 2008). There are no generally accepted principles for participant selection or sample size in qualitative research; rather focus is on the quality of information obtained. At other times some individuals with potentially critical information may refuse to participate in the study for various reasons.

Selection of institutions and participants can also be described as a limiting factor because the sample tends to involve only well known names. This may lead to a situation whereby individuals with crucial information are overlooked during participant recruitment.

Bias can lead to incorrect representation of the actual facts. In many ways, I was an insider in this study. Having been brought up in Africa, educated at an African university, the University of Nairobi in Kenya and worked as a scientist at a health research institute in Africa, I shared the social world of my participants and understood their everyday challenges. When a common culture is shared with research participants, our own or the respondent’s biases, assumptions and beliefs can intrude into the analysis (Corbin & Strauss, 2008).

Time and place also affect the validity of the study. This data is reflective of the time period interviews were conducted and it expresses the opinions of the interviews not necessarily any one individual, institution or nation. However it is meant to capture and understand the collective views of all participants. The situation may have changed over time.
3.8 Research ethics

All the three studies were approved by the University of Toronto Research Ethics Board. It was categorized as a minimal risk study hence received an expedited review. Written free and informed consent was obtained from each participant before the interview proceeded and after the details of the study and the nature of their participation had been carefully explained. All digital files and transcripts are kept on a secure, password-protected computer with restricted access. All field notes are stored in a locked cabinet at the McLaughlin-Rotman Centre for Global Health. The confidentiality of the information was discussed with the key informants.

Standardized databases of raw data will also be kept in order to facilitate secondary analysis of the data when possible. The stored database consists of:

- Case study notes (including interviews, observations, document analysis, notes by interviewer)
- Case study documents organized in an annotated bibliography to facilitate later use
- Narratives
- Raw audio data

All material will be stored for a period of five years from the close of the study. Data will be locked in a secure cabinet in our research offices in Toronto to which only members of the research team will have access. Likewise, all electronic files pertaining to this study will be stored on password-protected computers with access restricted to members of the MRC research team on this and related projects.
3.9 **Dissemination of results**

In order for the results of this study to have the desired impact, it is necessary to disseminate them to target audiences identified in chapter 1. The results of the study were disseminated through workshops, conferences and publications.

3.9.1 Workshop

A workshop was organized in Kigali Rwanda between 23rd June and 25th June 2008 during which the results of the Rwanda case study were presented back to the interviewees and to other stakeholders in Rwanda’s science based health innovation system (appendix H for workshop summary). The objective of the workshop was among other things to validate these results and to develop a way forward in trying to implement the recommendations of the study. During the workshop it was agreed that the best way to implement the study findings was to bridge the gap of weak synergies. It was proposed that a Life Sciences Convergence Centre (Kamunyori et al., 2008) be established.

Following the workshop, I became directly involved in a team that developed a business and operational plan for the Life Sciences convergence centre. We then travelled to Rwanda and presented the business and operational plans to the Minister in President's Office in Charge of Science, Technology, Scientific Research, and Information Communication Technologies who then presented it to the Rwanda cabinet. As a result, a line item for the Life Sciences convergence centre was included in the National 2009/2010 budget of Rwanda.

In 2009, the portfolio of science in Rwanda was moved to the Ministry of Education. We then held a meeting with the Minister of Education and several stakeholders including government representatives, the private sector and research institutions. Three pilot projects for the convergence centre were selected. These include

1. Softening of Banana fibers for textile production.
2. Increase yield of seri-culture for textile production
3. Value addition to pyrethrum

A due diligence study was then conducted on these three projects and subsequently an initial amount of money was disbursed to the banana fiber and the seri-culture project.

3.9.2 Conferences

In order to reach a broad diversity of stakeholders, the results were also disseminated at various international conferences including the Biovision Alexandria conference 2010 and Globelics 2010.

3.9.3 Publications

The main dissemination channel is through scientific publications.
Chapter Four: RESULTS: NATIONAL LEVEL CASE STUDY

4.1 Introduction:

This chapter discusses the results of Study 1, the case study at national level, by reproducing in full, a manuscript published in BMC International Health and Human Rights Journal.

The chapter relates to specific objective 1) National level. The purpose was to describe and analyze health innovation and biotechnology in a country. The main objective was to understand the actors, and the system, highlighting its strengths and identifying its weaknesses. This objective was explored through the following research questions:

a) What is the role of government as a facilitator and policy formulator in the system of health innovation?

b) What is the capacity of the country’s health research institutions for creating and undertaking research and development (R & D)?

c) What is the capacity and sustainability of the private sector to acquire and utilize local R & D outputs?

d) What is the role of foreign donors and international organizations in innovation in countries?

e) What are their linkages/interactions between actors in the system of innovation?
4.2  

Science-Based Health Innovation in Rwanda: unlocking the potential of a late bloomer

Published previously as:


Authors' contributions

Kenneth Simiyu, Abdallah S. Daar, and Peter A. Singer contributed to the concept and design of this study and participated in site visits, analyzed the findings, and participated in manuscript development. Mike Hughes participated in site visits, and participated in manuscript development.
4.2.1 Abstract

Background

This paper describes and analyses Rwanda’s science-based health product ‘innovation system’, highlighting examples of indigenous innovation and good practice. We use an innovation systems framework, which takes into account the wide variety of stakeholders and knowledge flows contributing to the innovation process. The study takes into account the destruction of the country’s scientific infrastructure and human capital that occurred during the 1994 genocide, and describes government policy, research institutes and universities, the private sector, and NGOs that are involved in health product innovation in Rwanda.

Methods

Case study research methodology was used. Data were collected through reviews of academic literature and policy documents and through open-ended, face-to-face interviews with 38 people from across the science-based health innovation system. Data was collected over two visits to Rwanda between November – December 2007 and in May 2008. A workshop was held in Kigali on May 23rd and May 24th 2009 to validate the findings. A business plan was then developed to operationalize the findings.

Results and Discussion

The results of the study show that Rwanda has strong government will to support health innovation both through its political leadership and through government policy documents. However, it has a very weak scientific base as most of its scientific infrastructure as well as human capital were destroyed during the 1994 genocide. The regulatory agency is weak and its nascent private sector is ill-equipped to drive health
innovation. In addition, there are no linkages between the various actors in the country’s health innovation system, i.e. between research institutions, universities, the private sector, and government bureaucrats.

Conclusions

Despite the fact that the 1994 genocide destroyed most of the scientific infrastructure and human capital, the country has made remarkable progress towards developing its health innovation system, mainly due to political goodwill. The areas of greatest potential for Rwanda are in traditional plant technologies. However, there is need for investments in domestic skill development as well as infrastructure that will enhance innovation. Of foremost importance is the establishment of a platform to link the various actors in the health innovation system.

4.2.2 Background

In the years between 1996 and 2005, Rwanda registered an impressive annual economic growth rate averaging about 8 per cent.39 This growth took place despite the fact that Rwanda is one of sub-Saharan Africa’s smallest countries, and had just emerged from a traumatic history of political upheaval that culminated in genocide in 1994. The country’s population of 9.5 million40 inhabits a landscape of only 26,000 sq km, making it one of Africa’s most densely populated countries. Its domestic economy is characterized by low technology enterprises dominated by commodity trading and basic services. The country is faced with many structural challenges—it is land-locked, has very few natural resources, and relies almost entirely on earnings from exports of high volume and low value agricultural products such as tea and coffee, making it very susceptible to the whims of the global market.

Rwanda’s economic growth, so soon after the destruction of the country’s infrastructure and human capital during the genocide, was a result of several factors including strong political leadership, much international support, and the zeal and optimism of its people. Although the economic growth rate dropped to 5% in 2008\textsuperscript{41}, mainly due to bad climatic conditions that affected its agricultural exports, it still compares favourably to most countries in sub-Saharan Africa.

Rwanda’s impressive economic growth has not, however, yet been fully translated to improved socioeconomic status for all segments of the population. The country’s per capita GDP at only US $230 (41% from agriculture, 38% from tourism and 21% from industry, mainly construction) means that poverty levels are still high\textsuperscript{42}, with more than 64% of all households in the country living below the poverty line. 85% of those living below the poverty line are in rural areas. Only 41% of the population had access to safe drinking water in 2008, while just over 50% had access to safe sanitation\textsuperscript{43}. As a result, the incidence of diarrheal diseases is high, partly contributing to the high infant mortality rate which, at 119 per 1000, remains well above sub-Saharan Africa’s average\textsuperscript{44}. Such factors coupled with the high incidence of malaria and HIV/AIDS limit the average life expectancy to only 49 years.

Rwanda’s national innovation system may be described as still very underdeveloped, but changes that have occurred in the country’s economy since the genocide are positively reflected in the innovation system. The country still ranks very low in knowledge

\textsuperscript{41} WorldBank. 2009 data from Development Economics LDB database. \url{http://data.worldbank.org/country/rwanda}

\textsuperscript{42} WorldBank. 2009 data from Development Economics LDB database. \url{http://data.worldbank.org/country/rwanda}

\textsuperscript{43} WorldBank. 2009 data from Development Economics LDB database. \url{http://data.worldbank.org/country/rwanda}

\textsuperscript{44} World Health Organization (WHO), Rwanda Health System Fact Sheet; 2009. \url{http://www.who.int/countries/rwa/en/}
indicators, having an innovation index of 1.22 out of 10\textsuperscript{45}, having less than 30 ISI publications between 2002 and 2004 (Mouton & Waast, 2009) and zero patents between 2000 and 2004 (Pouris & Pouris, 2009b). However it has made tremendous investments to improve this, including, for example, providing universal free primary school education, expanding higher education opportunities, and establishing collaborations and training programs with foreign universities. In fact, the number of students in higher education has risen from only around 1,000 students in one University in 1994 to more than 27,787 in 2005, with 39\% of them female\textsuperscript{46}. The domestic scientific skill base remains weak, but the government is attempting to counter this by pursuing a very liberal policy towards hiring of appropriate expatriate staff, e.g., nationals of the East African community member countries do not require work permits to work in Rwanda. The government is also encouraging members of the Rwandese diaspora to lend their expertise. To bolster the nascent private sector and the almost non-existent manufacturing base, reforms have been introduced to ease the cost of doing business in Rwanda. These include hastening the pace of registration of new businesses as well as increasing efficiency in enforcing contracts (WEF, 2009).

In this paper we present research on science-based health innovation in Rwanda, including biotechnology. By science-based health innovation, we mean technological innovation across a spectrum of sophistication, from vaccines, pharmaceuticals, and medical devices to some plant medicines where attempts to scientifically standardize or characterize medicines have been made. We take a broad definition of innovation as not only new-to-the-world innovation, but also the diffusion, adaptation and use of technologies. We use the OECD definition of biotechnology: ‘the application of science and technology to living organisms, as well as the parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services’ (van Beuzekom & Arundel, 2009).


The purpose of this paper is to describe and analyze Rwanda’s science-based health innovation using an innovation systems framework, which takes into account the wide variety of stakeholders who contribute to the innovation process and emphasizes the dynamic interaction and knowledge flow between them (Lundvall, 1992). To date there has been little research on science-based health product innovation in Rwanda. As far as the authors are aware, this is the first study to explicitly look at this topic in Rwanda.

The study was undertaken at the invitation of the former Minister in the Office of the President in charge of Science and Technology. The 1994 genocide marked a watershed moment for the country in general and the national innovation system in particular. Most of the already modest research base and private sector was destroyed. Our evaluation of the innovation system has this background context in looking at developments in the post-genocide period of the last 15 years.

4.2.3 Methods

A case study research methodology was used in this study (Yin, 2008a). Data were collected through reviews of academic literature and policy documents and through open-ended, face-to-face interviews in Rwanda. Interviewees were identified through purposive and snowball sampling; we interviewed 38 people from across the science-based health innovation system, including government officials (n=8), researchers in research institutes and educational institutions (n=11), entrepreneurs (n=6), international donors (n=2), and non-governmental organization representatives (n=5), over two visits to Rwanda between November – December 2007 and in May 2008. Given the important role of the members of the diaspora, we also interviewed 6 members from them. Following the interviews, a workshop was held in Kigali on May 23rd and May 24th 2009 involving the interviewees and other stakeholders to validate the findings. A business plan was then developed to operationalize the findings. We report the findings of our case study analysis below.
All quotes are from the interviews unless noted, and with permission. This study was approved by the Office of Research Ethics of the University of Toronto.

4.2.4 Results and Discussion

In the following sections, we describe and discuss Rwanda’s science-based health innovation system.

Government

The integration of science and technology into the country’s economic development has been given prominence in Rwanda since 1994. President Kagame has emphasized “the imperative of focusing and utilizing science and technology,” to effect the country’s and Africa’s socioeconomic transformation. In a speech to the 8th summit of the heads of state of the African Union, President Kagame reiterated the importance of innovation, stating, “It is about applying science and technology holistically - in all levels of education and training, in ‘commercializing ideas’, developing business and quickening the pace of wealth-creation and employment-generation, in enabling government to provide better services, and indeed in providing basic tools to society at large for self- and collective betterment.”

The guiding document for recent growth in science and technology in Rwanda is the 2006 National Science, Technology, Scientific Research and Innovation policy. Included in the policy are plans “to apply science to Rwanda's problems in health, agriculture and the environment” by increasing crop yields and improving animal husbandry through the use of biotechnology. In addition, the policy paper envisions

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setting up district-level 'innovation centers' and national technology parks to encourage research and development, particularly by small businesses.

Science and technology activities in Rwanda were transferred to the Ministry of Education in 2009. Prior to that, the Ministry in the Office of the President in charge of Science and Technology was the central agency in Rwanda’s science and technology model, and directed both funding and research orientation. However, it was understaffed, with only four staff who had to achieve the wide goals of the ministry as well as to coordinate all science and technology research and all aspects of information communications technology in Rwanda.

The Ministry’s 2009/2010 budget shows enhanced commitment to innovation, with line items included for establishing linkages between academia and industry and for strengthening intellectual property.

Though the country lacks a biotechnology policy, this remains one of the priority areas as alluded to by the then Minister of Science and Technology Prof. Romain Murenzi who when interviewed said, “I was thinking of the need to establish a biotechnology authority that will integrate biotechnology in health and agriculture”. However, a national biosafety framework49 was drafted in 2005, mainly to protect human health and the environment due to applications of biotechnology.

Rwanda’s public health goals are spelled out in the “Health Sector Policy-Government of Rwanda” document published in 200550 among which is the improvement of the availability of quality drugs, vaccines, and consumables and a goal to strengthen national referral hospitals and research and treatment institutions through collaboration with other

ministries and agencies. Within this document most of the research focus is limited to clinical aspects of health as opposed to health innovation.

As a “Least Developed Country”, Rwanda in 2008 became the first country to take advantage of the World Trade Organization (WTO) amendment to the TRIPS (Trade Related aspects of Intellectual Property) Agreement\(^{51}\), when it awarded a tender to the Canadian generic manufacturer Apotex to manufacture the triple combination AIDS drug "Apo Triavir" on its behalf. The first shipment of 6.8 million pills arrived in Rwanda in September 2008. The objective is to increase accessibility to cheap anti-retroviral (ARV) drugs to people with AIDS in Rwanda, many of whom are poor. Government officials stated that they hope by 2016, when the TRIPS agreements take effect, Rwanda will have developed capacity to manufacture its own pharmaceuticals.

An effective intellectual property regime is needed to support innovation in Rwanda. Despite an intellectual property law being passed by parliament in 2008, information has yet to reach scientists, and this law has yet to fully take effect. As put by Mark Bagabe, former Director-General of the National Agricultural Research Institute (ISAR), “We really have not internalized the need to patent our research. We are still rebuilding and focused on basic research and publication. In fact, as an institute, we have lost so much patentable information because of this”. There have been several missed opportunities where Rwanda could have benefited, but because there are no proper policies on innovation management, the country has not benefited. For example, a fertilizer was formulated at the Institut de Recherche Scientifique et Technologique (IRST) by a scientist who refused to disclose his formula; when he moved from the institution, he went away with the knowledge. Bean seed varieties developed at ISAR have also been found being marketed in countries such as Malawi, yet the Institute does not receive any royalties. And sericulture lines developed by ISAR are not shared with the textile industry in Rwanda.

\(^{51}\) http://www.wto.org/english/tratop_e/trips_e/wt1641_e.htm
Rwanda is a member of the WIPO convention, the constituent instrument of the World Intellectual Property Organization. However, there are no IP attorneys in Rwanda and respondents in this study doubted whether the country’s judiciary was sufficiently equipped to handle IP disputes. Another stated limitation which is common to many African countries was the high cost to file, maintain, and enforce patents, all which are the responsibility of the inventor; hence if the invention has no immediate financial returns, there is reduced willingness to attempt to patent.

Rwanda’s drug and medical product regulatory capacity is also very limited. The Food and Drug authority has just been established but has yet to become fully operational. Limited staffing and infrastructure issues, as well as the porous nature of Rwanda’s borders, mean that it is difficult to enforce drug quality and drug registration. Counterfeit products have been found in pharmacies in Rwanda (Kayumba et al., 2004) and this is a drain on the economy, patients are wasting money, and it is a significant health risk to the population.

**Research institutes and universities**

Like many African countries, the largest and most active R & D institutions in Rwanda are public sector ones involved in agricultural research. This is not surprising, as the economy is heavily agrarian. The main focus has been rural development and poverty alleviation, with little emphasis on basic and applied R &D. Up until 1994, political upheavals, changing budget priorities, staff purges due to ethnic wrangles, and generally poor morale left institutions incapable of carrying out their core mandates. Since then, investments in science and technology by the government and donors have improved the situation.
At the base of the educational system, 96% of primary-school age children now receive free education\textsuperscript{52}. The percentage of students progressing from primary school to secondary school is still low, perhaps due to absence of universal secondary school education. But overall, there has been a very significant increase in the number of students graduating from institutions of higher learning in Rwanda over the last 15 years.

The number of students in higher learning institutions increased from 10,000 in 2002 to 27,787 in 2005\textsuperscript{53}. Rwanda has six public and several private higher education institutions\textsuperscript{5455}. Data from the 2003 census showed that there were then 0.5% of university graduates in the population, compared to the African average of 4%. However, the gross enrolment rate at tertiary level was 3.2%, which is regionally comparable. Until recently there was no graduate training at the National University of Rwanda, forcing many students to be sent abroad for training.

\textit{Institute of Scientific and Technological Research}

The Institute of Scientific and Technological Research, also known as the Institut de Recherche Scientifique et Technologique (IRST), was established in 1989. It is the country’s premiere medical research institute, including research in phyto-medicine, biodiversity, alternative energy sources, environmental studies, and other fields related to medicine. Its website indicates that there is a Department of Biotechnology, but a visit to the institution revealed that this has not yet been established. The Institute has acknowledged the importance of domestic innovation and has established an innovation and technology transfer unit, as well as organized seminars to sensitize its scientific staff on intellectual property management since 2005. According to the Institute’s Director General Dr. Jean Nduwayezu, in 2007 the institute had a total of 96 staff (88 involved in

\textsuperscript{54} United Nations Development Programme (UNDP): Rwanda Annual Report; 2000
research) but only 6 PhDs (2 Rwandese nationals and 4 foreigners). He also stated that the optimal number of staff required is 121, hence there is a shortfall of manpower.

The Centre for Research in Phyto-medicines and Life Sciences at IRST carries out research in traditional medicines, by liaising with traditional healers and carrying out safety and anti-microbial efficacy tests. Material is sent to international laboratories, mainly in Europe, to carry out further investigation on plants that look promising. This has proved difficult as they first have to identify effective partners abroad. In some cases, results of material sent abroad are never communicated back to the scientists. Scientists expressed fear that they could be losing intellectual property this way. As one scientist remarked, “Sometimes all it needs is for an experienced scientist with the necessary equipment to establish anti-microbial properties of a plant. They then go ahead and make derivatives from it that are active against different pathogens and patent it claiming it to be theirs”.

Currently the main focus is testing for toxicity using mice on traditional plants submitted by the traditional healers. After ascertaining safety, the institute’s logo is usually affixed on the product which allows the traditional practitioner to market the product. Examples of traditional medicine extracts now being marketed include products for such mild common ailments as diarrhoea and common colds as well as ointments to relieve pain. An earlier survey of traditional medicinal products owed examples of such medicines to include an anti-spasmodic syrup from Datura stramonium (Gifurina), anti-cough syrup from Plantago lanceolata (Bentakor), cough syrups from the mixture of Eucalyptus globulus and Datura stramonium (Tusinkor), and from Eucalyptus globulus, Datura stramonium and Thymus vulgaris (Tumitusilinga), a mouth disinfectant solution from Eucalyptus globulus and Mentha sacchalinensis (Kanwalina), an anti-arthritic formulation from Capsicum frutescens, an anti-inflammatory ointment from Calendula officinalis (Calendula) and an antiscabies ointment ‘Tembatembe A’ containing a rotenone compound from Neorautenenia mitis, which was used successfully on prisoners.
National Agricultural Research Institute

The National Agricultural Research Institute, also known as the Institut des Sciences Agronomiques du Rwanda (ISAR), is Rwanda’s major agricultural R&D agency. ISAR, the oldest scientific research institution in Rwanda, was rebuilt after the 1994 war; this included the construction of new laboratories and installation of modern scientific equipment. Many staff members have received international training (Masters and PhD) and today the institute can be described as the institution that has the best capabilities within Rwanda to carry out basic biotechnology research. The institute has the capacity to carry out limited molecular biology techniques, tissue culture, and food fortification. However, at the time of the study it had no clear IP policy and very little focus on innovation. Like most other research institutes in Rwanda, there had been very little linkages with the private sector.

In addition to the above two research institutes, higher education institutions in Rwanda are participating in research.

National University of Rwanda

The National University of Rwanda is the country’s biggest university and was established in 1963. Located at Butare, it offers a wide range of degree programs. It has also developed a new strategic plan in which great emphasis has been placed on scientific innovation. The Faculty of Agriculture and the School of Medicine are the departments that are actively involved in health related research. However, because of the high student to staff ratios at the university, resources are heavily skewed towards teaching at the expense of research. As one professor remarked, “Our focus at the moment is to teach. Because we have very many students compared to the number of staff, we cannot conduct any research.” Other limitations include lack of scientific infrastructure as well as general funding. Currently, most health research is limited to epidemiological studies.
and clinical research on behalf of international organizations and foreign university researchers.

*Kigali Institute of Science and Technology*

Kigali Institute of Science and Technology (KIST) was the first public technological institute of higher learning in Rwanda. Though originally established as a technology and engineering institution in 1997, it has expanded its curriculum to many other areas including health sciences and now offer degrees in various subject areas. In 2009, it established a faculty of medical biotechnology, to train both undergraduate and graduate students. As the Rector, Prof. Abraham Atta Ogwu said, “We realized the future importance that medical biotechnology will play in trying to address Rwanda’s health needs, and that is why we decided to be the first institution in Rwanda to offer training specifically geared towards medical biotechnology”. KIST has also established the Centre for Innovation and Technology Transfer to develop appropriate technology solutions for rural areas and has an incubation facility that nurtures young entrepreneurs, providing basic facilities and business management training services to them.

According to Ministry of Science officials, KIST is more adoptable to the country’s needs because it does not have historical bureaucracy that other institutions that have been there for a long time face. In addition there are many international visiting scholars at the institution as well as international collaborative agreements with other institutions enabling knowledge exchange that is critical for developing skills in innovation.

Though it was difficult to obtain, for any of the country’s institutions, the allocation of research budgets across salaries, and capital costs, there was clear evidence that the bulk of resources are currently allocated towards operating costs, thereby affecting the efficiency of R & D.

*Private sector*
Rwanda’s private sector is nascent, with most businesses being small scale and with low technology enterprises. From the interviews many entrepreneurs were young and were western educated mainly in the United States and Britain and had only returned to the country in the late 1990s or early 2000’s.

Private sector investors have not generally been involved in exploiting any potential opportunities from research, let alone from research in health or biotechnology.

One firm that has tried to produce local health products is Ikirezi Natural Products, a firm that has been involved in extraction and export of geranium oil, which is used as an essential oil in remedies for dermatological conditions. According to the founder, this has generated significant economic benefits to farmers, as the value from the same acreage of land for geranium is much higher than for coffee and tea – demonstrating the potential of alternative crops.

Also interested in health technology is Rwanda’s largest industrial manufacturer, Utexrwa, which specializes in textile manufacture. The company CEO has expressed interest in manufacture of pyrethrum impregnated mosquito nets which would serve two purposes: provide a market for pyrethrum that is currently being exported unprocessed outside the country, and save the importation of long lasting mosquito nets. There are talks between the firm and universities in Canada about developing technology that could use pyrethrum to replace synthetic pyrethroids on long lasting insecticide-treated mosquito nets.

One other area examined in this study was access to risk capital and credit. We identified at least four venture capital firms in the city of Kigali, plus several banking and micro-finance institutions. The Rwandan Enterprise Investment Company (REIC) is the largest such provider of risk capital. The company’s legal foundation, established by an act of Parliament, is viewed as a source of strength as it is a public institution with private
sector goals. Its primary responsibility is to government, but it has autonomy in its investment decision making. The organization has the mandate of financing projects which have both commercial and social benefits. According to the CEO of REIC, the major limitation to investment in health R & D has been the inability for them to determine the commercial viability of health research in Rwanda. “We have this mandate towards looking at key core areas that need financing because nobody else is willing to finance them” says Mike Kagwa, its CEO. “If health is an asset that can be structured, we will be in it. Not many people know how to structure health research as a viable asset and we do not know where the commercial gain is, except social benefits”.

Foreign venture investors, especially American firms, can also be found in Rwanda. While many are driven by their conscience to help rebuild the country, a number of them are simply looking for potential profits that can be reaped from a country that is starting from scratch, as there is very little domestic competition. “My investors are hard-nosed capitalists”, says American trained Antoine Bigirimana, CEO of Kigali based Thousand Hills Venture Capital. “They are simply looking for ideas that are easy winners”.

However, there is a lack of connection between capital providers and researchers in the university and research institutes. This is due to the absence of knowledge flow and of venues in which they can meet and exchange ideas. When asked, most researchers in Rwanda were unaware of the existence of local venture capitalists, while the venture capitalists were also unaware of the fact that there might be technologies stagnating on shelves in local institutions.

Private sector entrepreneurs in Rwanda are organized under the Rwandan Private Sector Foundation. We were informed by one of the interviewees that this umbrella organization of businesses in Rwanda has eight regional centres where it trains small business management skills. There are also a number of micro-finance institutions that mainly support small businesses by providing them with loans and business training.
The only pharmaceutical manufacturer in Rwanda is the government owned Pharmaceutical Laboratory of Rwanda (LABOPHAR). After years of loss making it was recommended for privatization. The company was initially set up to manufacture quinine and a variety of generic products, but has been limited to manufacturing intravenous fluids and water for injection, i.e. bulk products that cannot be imported and yet are necessary for the country’s hospitals. According to some interviewees, the poor performance of the company is mainly attributed to lack of technical know-how, lack of infrastructure, poor management, and the fact that it was a government-run institution without the drive of private entrepreneurship. It thus became a burden to the Rwandan tax payer, hence its privatization.

Drug distribution in Rwanda also appears ad-hoc, mainly because the drug regulatory agency has not been fully staffed. Individuals can import any products without any restrictions or assessment on their quality. As such, many pharmacies in Rwanda import directly, mainly from India and Kenya. CAMERWA is the government agency charged with drug procurement and distribution and mainly supplies government-run hospitals with drugs, all of which are funded by donor agencies. The agency is reasonably well staffed at the national office, but lacks the infrastructure needed to ensure successful national distribution.

Innovation is also affected by market factors. The domestic market in Rwanda is small, both in size and purchasing power, hence demand for products is limited. This tends to affect the quantity and type of products that are developed for the Rwandan market by domestic and international enterprises.

Overall, Rwanda’s general business climate is well-regarded in comparison to its neighbouring countries in the East African Community and in Africa in general. For example, Rwanda has less corruption and bureaucracy than the regional standards, and the time taken to start a business is shorter than the average for sub-Saharan Africa – all factors which make local science-based health innovation easier. Some business issues
that Rwanda is currently addressing include legal and regulatory constraints as well as improvements to enforcement and employment practices.

**NGOs and Donors**

Non-governmental organizations and donors also influence Rwanda’s science-based health innovation. The Rwandan government receives more foreign aid per capita than most countries in Sub-Saharan Africa\(^\text{56}\). This aid is delivered through a mix of budget support and project financing. At its peak in 2005, 60% of the national budget was directly funded by donors. Many interviewees said that because scientific research in Rwanda is largely financed by donors and multilateral development banks, channelled through both the national government and project support directly to various institutions, the allocation of resources across various lines of research reflects donor influence. Most donors fund specific programs within their traditional areas of interest. Thus the European Union funded construction and equipment of a coffee research laboratory at ISAR to stimulate coffee research, reflecting their priority of agriculture.

The government has made efforts to gradually reduce this to just over 40% in 2009. According to officials in the Ministry in charge of science, the main donors in science and technology are the World Bank, the African Development Bank, and the British international development agency, DFID. DFID is currently assisting in the development of an institutional framework within the Ministry of Science and Technology that will, among other things, support innovation platforms. The World Bank is working on programs that enhance scientific capacity, focusing on value addition of agricultural products. The aim of this World Bank project is to foster economic growth by creating jobs and wealth through building an economy that is driven by innovation and higher-value production systems.

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In 2006/7, the African Development Bank, through the science and technology sector budget support, assisted in drafting the Science and Technology in Education work plan. This plan, which has been put in place, aims to foster the teaching of science and technology from the primary school level with the provision of science corners in all schools. At the secondary school level, plans include the building of science labs. Vocational and technical schools in Rwanda are also to be renovated and equipped to provide effective education geared to the labor market.

Ministry of Science officials also told us that collaborative programs with institutions in the US and other developed countries have also been established with the main purpose of providing training to Rwandese scientists. These include Carnegie Mellon and Massachusetts Institute of Technology (MIT) whereby students from Rwanda are given scholarships to train at these institutions in the fields of computer science and engineering. The Government of Rwanda has also established a Presidential Scholars program in collaboration with universities in the US that enables Rwanda’s best math and science students to receive four-year scholarships to do their undergraduate studies at US colleges and universities. The major institution supporting the Presidential Scholars program is Oklahoma Christian University. The focus of the studies are civil and electrical engineering, computer science, chemistry, and architecture, and biotechnology, areas of study deemed critical to Rwanda’s long-term, economic development plans.

The National Treatment and Research AIDS Center (TRAC) is a non-governmental organization that tries to shape health policy in Rwanda using treatment outcomes. TRAC partnered with the software company Voxiva to develop an integrated software system for monitoring diseases in Rwanda. Using both web-based software and mobile phones, TRACNET collects, stores, retrieves, displays and disseminates critical program information, as well as managing drug distribution and patient information related to the care and treatment of HIV/AIDS.
The displacement of many of Rwanda’s citizens because of historical strife resulted in a large Rwandan diaspora. According to the ministry of Foreign affairs, an estimated 6 million people of Rwandese descent live abroad, mainly in Europe and North America; this number is over half the entire population of people living in Rwanda. This significant resource can act as a source of revenue through remittances and direct investments, as well as a pool from which to draw ideas, skills, attitudes and technologies. Discussions with Jean Kimanzi, President of Rwandan Diaspora, revealed that there are already two programs – Transfer of Knowledge Through Expatriate Nationals (TOKTEN) and MIDAS – that enable qualified Rwandese in the diaspora to travel back to Rwanda periodically to assist in transfer of knowledge. These programs aim to supply Rwanda with short-term expertise not readily and immediately available locally. “The environment is right. There is political will and Rwandese should take advantage of this to give something back to their country” remarks Dr. Kimanzi.

4.2.5 Conclusions

Strengths and Good Practices

Rwanda’s science-based health innovation system including biotechnology has several strengths, which include liberal policies on employment of expatriates, the clustering of its academic and research institutes in one main geographical area, and the multi-lingual nature of the population, which means that it is easier for Rwanda to trade with many countries.

Perhaps the greatest strength of Rwanda’s science and technology system is the political support and dynamic leadership that the country is currently experiencing, especially from the country’s President, Paul Kagame. This was cited by many respondents who also mentioned the fact that the country has made dramatic investments in science and
technology. According to the President, Rwanda currently invests 1.6% of its GDP on Science and Technology\textsuperscript{57}. The country has also developed a strong science, technology and innovation policy, meaning that Rwanda has realized the need to incorporate STI in its economic development agenda. Activities to implement the policy have already started and the World Bank carried out a needs assessment based on the STI policy and recommended practical solutions to some of Rwanda’s problems (Watkins & Verma, 2008). The main area of focus was value addition to agricultural products. The 2009 government budget provided funds (approximately 100,000 dollars) to support innovation activities. These funds can be accessed by any scientist or entrepreneur. An initial disbursement of these funds was made to support projects in KIST and ISAR; one on the use of banana fibres in textiles and the other on sericulture development in Rwanda. From interviews with government officials, it also appears that the government readily welcomes donors and international institutions that are willing to help it strengthen science activities in Rwanda.

However, while Rwanda has a good STI policy, STI activities in the country are mainly focused on the development of information technology with little focus on health and health biotechnology. The reasoning behind this is that Rwanda aims to become the information technology hub of Africa. Information technology has become very useful in supporting health programs in Rwanda, as evidenced from the TRACNET program. However, interviewees mentioned that health innovation is not sufficiently mentioned in the STI policy.

The main opportunities in science-based health innovation and biotechnology for Rwanda are in traditional plant technologies (see Table 4 for selected opportunities). Interviewees repeatedly cited this as the area of greatest potential. Reasons included the existence of IRST (an institute that has some capacity to carry out research in traditional medicines), the ready availability of a variety of traditional plants, and the experience of traditional

plant healers. Health-related information technology was also identified as an area with great potential. Many interviewees gave the reason for this to be the well developed information infrastructure in the country, as well as the government’s inclination to support information technology policies.

4.2.6 Recommendations

From the interviews, we can conclude that there are specific challenges that need to be overcome for Rwanda to successfully exploit its science-based health innovation and biotechnology. When we interviewed the management of the various research institutions, they cited deficiency in scientific infrastructure and a shortfall in the number of trained scientists who are capable of carrying out advanced health biotechnology research as one of the major challenges. Specifically, many interviewees cited the low number of people trained in molecular biology techniques as a hindrance to development of the sector. Post-graduate opportunities within Rwanda are limited, particularly within health biotechnology.

In addition, there is a skewed distribution of health researchers in favour of teaching at academic institutions. This has contributed to the dismally low number of research publications by local Rwandan scientists, which total only 30 research articles published between 2002 and 2004. From the interviews, many of the scientists did not appear able or sufficiently motivated to pursue entrepreneurial activities as most do not consider research to be rewarding.

The brain drain that occurred during earlier years in the country’s history continues to plague science and technology. This was made worse by the genocide, during which scientists were among those who were killed or fled to other countries in the region and abroad. While a few have returned and formed part of the interview pool, many are still abroad. However, this may also represent a strength, as the Rwandan diaspora consists of highly qualified individuals who left the country either as refugees or to pursue higher
education in the West. When interviewed, many members of the diaspora said that since they are now occupying senior positions in new countries, they are unwilling to return to Rwanda, but they could lend their skills to support development of health biotechnology if appropriate policies are put in place.

Another problem is brain drain within the country, mainly as a result of a serious mismatch between capabilities, opportunities and compensation of scientists within Rwanda. Interviewees repeatedly cited the efflux of researchers from university and research institutes towards sectors that do not engage in research, such as NGOs that offer attractive work environments and higher salaries.

Discussions with scientists showed that a career in politics has become a very attractive field for Rwandan scientists. Indeed, a close examination of the Rwandan Cabinet and Parliament reveals a contingent of very highly trained professionals, many of whom possess advanced degrees in biotechnology, engineering, or health and significant research experience. This illustrates the internal brain drain phenomenon, although it may be argued that having a scientifically literate political establishment has contributed to increased support for science and technology.

We can deduce from the study that science-based health innovation and biotechnology in Rwanda is currently fragmented, with training and scientific research falling under many different agencies. For example, universities fall under the Ministry of Education, while research institutes fall under different ministries including the Ministry of Agriculture (e.g. ISAR, ISAE) and the Minister in President's Office in Charge of Science, Technology, Scientific Research, and Information Communication Technologies (e.g. ISTR). From the interviews it was apparent that the government has continued to fund R&D institutes and universities without paying much attention to the quality of research being conducted the use of research outputs, or the relationship of research to the country’s economic, scientific, or market priorities. Neither does it appear that efforts have been made to stimulate linkages between the private sector and the universities and
research institutes in Rwanda. Most scientists interviewed did not seem to know what other research institutes were doing, nor were there institutional mechanisms to outsource their knowledge to the private sector players like venture capitalists.

In order to successfully exploit the potential of science-based health innovation and biotechnology in Rwanda, several recommendations can be made.

Recommendation 1: Strengthen the skills base: For a country with limited resources like Rwanda, investment in knowledge arguably is critical to development. Rwanda should promote the training of its scientists in order to develop a scientific pool that can spur health innovation. This can be done through domestic, regional, and overseas institutions. We realize that this will require considerable resources, but one source of skills and training staff is the Rwandan diaspora who can be encouraged through incentives to provide short-term training to scientists in Rwanda. Attaching skilled members of the diaspora to universities in Rwanda will reduce costs of sending students abroad. Because of its strong links with international institutions, online courses could also be used whereby staff from western universities give lectures on scientific areas as well as on entrepreneurship.

Carrying out an audit of the personnel and scientific infrastructure available in Rwanda will help identify areas that need strengthening. To reduce brain drain, it is important that the government provides incentives through reasonable wages for scientists and clear promotion paths as well as facilities for scientists to be able to carry out their work. Institutions should develop IP policies that reward individuals who are innovative.

Recommendation 2: Encourage the establishment of R & D within private sector firms: The government can do this by creating a favourable business environment for firms that want to engage in R & D. Firms like Utexrwa which have already indicated willingness to engage in health innovation might be incentivized. This could be through tax incentives on research equipment and raw materials, as well as local “advance market
commitments”, whereby the Ministry of Health guarantees purchase of products developed locally as long as they meet internationally accepted standards. Strengthening of intellectual property regimes and increasing awareness of IP by scientists will be helpful. There is also need to support innovative activities by providing funds that scientists and entrepreneurs can access, such as prototype or product development funds in the form of grants or loans.

Recommendation 3: Establish a focal point for science-based health and biotechnology development: There is need to coordinate R & D and innovation at the national level. Currently, there is no National Science Council or Commission which could be the body charged with coordinating research in Rwanda. While the government has established the Rwanda Biomedical Centre (RBC) which merges 15 medical institutions in the country, the focus is limited to clinical research. A council would be charged with capturing the innovative components of biotechnology research. This body would direct sectoral policies – e.g. developing a national biotechnology policy – and could clearly define the priorities of the government in terms of health innovation development, as well as concrete actionable steps to realize these goals. It could also identify an institution that will be a centre of excellence for biotechnology. This centre could be equipped with individuals possessing the necessary skills to excel in biotechnology research, as well as the necessary scientific infrastructure, and a mandate to establish relationships between firms and research institutions.

Recommendation 4: Establish R & D infrastructure and platforms through which knowledge flows from the country’s research institutions will flow to firms in the private sector and vice versa: These could be in the form of physical platforms or virtual networks (Teng-Zeng F, 2009). The centres will be equipped with state of the art specialized equipment. From the interviews, scientists cited the lack of advanced equipment as a hindrance to R & D and gave examples of equipment like nuclear magnetic resonance (NMR) machines and high-performance liquid chromatography machines (Hulks) that do not currently exist in Rwanda. Many types of research
instruments are very expensive for individual institutes to buy and maintain. Such a centre can be centrally located, and its facilities accessed by scientists from various institutions as required.

The aim of this study was to describe and analyze Rwanda’s science-based health innovation and biotechnology sector. In doing so we also involved the stakeholders who constitute this sector in developing options to harness Rwanda’s assets and begin to overcome barriers.

Since the completion of our study, we have continued to work with the Ministry of Science and Technology and subsequently the Ministry of Education, to address some of the key challenges we identified in our case study. We jointly hosted a national life sciences workshop held in May 2008 in Kigali where we presented our case study results and recommendations, which were discussed with local stakeholders including government officials, the private sector and the research community. Stakeholders agreed unanimously with the results and recommendations, especially the need to increase knowledge flow. They supported the idea of developing a life sciences innovation center (Kamunyori et al., 2008). Since the meeting, an initial disbursement of funds to two projects has been done, and discussions are underway on where the initial start-up activities are to be physically located.

From the study, the main conclusion that can be drawn is that Rwanda is a late bloomer in science-based health innovation and biotechnology, mainly because of events preceding and during the 1994 genocide. There is very little innovative activity occurring in the institutions or in the private sector. The number of scientists is still very low, and even those who are present are not generally motivated to carry out innovation.

However, because Rwanda is still at an early stage in developing its institutions, it is well positioned to shape its institutions in line with current challenges in science-based health innovation and biotechnology; its institutions are not bogged down by the bureaucracy
and rigidity that characterize many more-established institutions in Africa. Many of the staff in its institutions are young and amenable to change, and could easily embrace innovation if properly motivated. In addition the country enjoys enormous goodwill among the donor community to implement many initiatives that the government proposes. It also has a large pool of skilled people in the diaspora who are willing to contribute towards developing their homeland. Building on these assets and strong political commitment, Rwanda has the potential to make effective use of science-based health innovation.

Table 4: Various products and processes being developed in Rwandan institutions

<table>
<thead>
<tr>
<th>Product</th>
<th>General Area</th>
<th>Organization</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traditional herbal medicines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Gifurina- <em>Datura stramonium</em></td>
<td>Anti-spasmodic</td>
<td>IRST</td>
<td>Whole plant extracts. Adoption of existing practices by traditional healers and carry out safety and efficacy tests</td>
</tr>
<tr>
<td>- Bentakor- <em>P. Lanceolata</em></td>
<td>Anti-cough</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Tusinkor- <em>E. globulus</em></td>
<td>Anti-cough</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Tumitusilinga- <em>T. Vulgaris</em></td>
<td>Oral disinfectant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Kanwalina- <em>M. Sacchalinensis</em></td>
<td>Anti-arthritic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Calendula- <em>C. officinalis</em></td>
<td>Anti-inflammatory</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Tembatembe A- <em>N. Mitis.</em></td>
<td>Scabies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Essential oils-Geranium</td>
<td>Cosmetics/Dermatology</td>
<td>IKIREZI Natural products</td>
<td>Extraction of essential oils from geranium plant</td>
</tr>
<tr>
<td>Intravenous fluids and water for injection</td>
<td></td>
<td>Laborphor</td>
<td>For use in hospitals, since transport costs for this bulky product are high</td>
</tr>
<tr>
<td>Pyrethrum treated long lasting mosquito nets</td>
<td>Malaria</td>
<td>Utexrwa</td>
<td>Concept under development with researchers from Canada</td>
</tr>
<tr>
<td>Health information technology software</td>
<td>Health IT</td>
<td>TRAC</td>
<td>Developing software for integrating health information, in partnership with Voxiva.</td>
</tr>
</tbody>
</table>
Chapter Five: RESULTS: INSTITUTIONAL LEVEL CASE STUDY

5.1 Introduction:

This chapter discusses the results of study 2, the case study at institutional level, by reproducing in full, a manuscript published in BMC International Health and Human Rights journal.

The chapter relates to specific objective 2) Institutional level. The unit of analysis was a public health research institution, KEMRI. The main research aim was to analyze the commercialization environment – the microeconomic and strategic conditions – that the health research institution is facing in its attempts to translate ideas and technologies into products.

The questions necessary to answer this were:

a) What is the organizational structure?

b) What is the institution’s research and development (R & D) capacity including examples of products being developed?

c) What is the organization policy towards Intellectual Property (IP)?

d) What strategies has the institution adopted regarding technology transfer either within the institution or eternally?

e) What are the challenges and barriers that hinder effective technology transfer?
5.2 Turning Science into Health Solutions: KEMRI’s challenges as Kenya’s health product pathfinder

Previously published as:


Authors' contributions
Kenneth Simiyu, Hassan Masum, Justin Chakma, and Peter A Singer contributed to the concept and design of this study, analyzed the findings, and participated in manuscript development. Kenneth Simiyu and Peter A Singer participated in site visits.
5.2.1 Abstract

Background
A traditional pathway for developing new health products begins with public research institutes generating new knowledge, and ends with the private sector translating this knowledge into new ventures. But while public research institutes are key drivers of basic research in sub-Saharan Africa, the private sector is inadequately prepared to commercialize ideas that emerge from these institutes, resulting in these institutes taking on the role of product development themselves to alleviate the local disease burden. In this article, the case study method is used to analyze the experience of one such public research institute: the Kenya Medical Research Institute (KEMRI).

Discussion
Our analysis indicates that KEMRI’s product development efforts began modestly, and a manufacturing facility was constructed with a strategy for the facility’s product output which was not very successful. The intended products, HIV and Hepatitis B diagnostic kits, had a short product life cycle, and an abrupt change in regulatory requirements left KEMRI with an inactive facility. These problems were the result of poor innovation management capacity, variability in domestic markets, lack of capital to scale up technologies, and an institutional culture that lacked innovation as a priority.

However, KEMRI appears to have adapted by diversifying its product line to mitigate risk and ensure continued use of its manufacturing facility. It adopted an open innovation business model which linked it with investors, research partnerships, licensing opportunities, and revenue from contract manufacturing. Other activities that KEMRI has put in place over several years to enhance product development include the establishment of a marketing division, development of an institutional IP policy, and training of its scientists on innovation management.
Summary
KEMRI faced many challenges in its attempt at health product development, including shifting markets, lack of infrastructure, inadequate financing, and weak human capital with respect to innovation. However, it overcame them through diversification, partnerships and changes in culture. The findings could have implications for other research institutes in Sub-Saharan Africa seeking to develop health products. Such institutes must do demand analysis, yet be prepared to face the unexpected and develop appropriate risk-mitigating strategies.

5.2.2 Background

A traditional pathway for developing new health products begins with public research institutes as generators of knowledge, and the private sector as the translator of the knowledge into actual ventures. In the developed world, for example, early product commercialization – defined as conversion of an idea or technology to a product or service that generates profits or has an impact on the lives of everyday people (J. S. Gans & Stern, 2003b) is driven by public research institutes and universities (Bartholomew, 1997; Godin, 2007; Mowery, 1992b). Notable health products commercialized this way include the Boyer–Cohen “gene-splicing” technique that launched the biotechnology industry, and diagnostic tests for breast cancer and osteoporosis (Siegel, Waldman, & Link, 2003a).

In the developing world, health products developed in public institutes and then transferred to the private sector include the first effective meningitis B vaccine, developed at the Cuban Finlay Institute and licensed to GlaxoSmithKline58, and the antimalarial drug arteether (a semi-synthetic artemisinin derivative), developed at India’s Central Drug Research Institute, now licensed to Themis Chemicals and sold in 48 countries(C. M. Morel et al., 2005b). In sub-Saharan Africa, an example of such a

transfer is the sickle cell drug Niprisan, developed by the Nigerian Institute of Pharmaceutical Research and licensed to Xechem (see the paper on Niprisan in this BMC series). Another example is the appetite-suppressing Hoodia plant, whose active ingredient was patented and out-licensed by South Africa’s Council for Scientific and Industrial Research (Al-Bader, Frew, Essajee, Liu, Daar, & Singer, 2009).

Many deaths due to disease continue to occur in sub-Saharan Africa, e.g. 90% of the 1 million malaria deaths and 40% of the 1.3 million TB deaths globally in 2008 were in sub-Saharan Africa. Yet less than 10% of global health R&D expenditures go toward developing solutions for the developing world, (commonly termed the 10/90 gap) (Al-Tuwajri et al., 2004). This has led to calls for countries in sub-Saharan Africa to develop their own products as a way of addressing local health problems (Juma & Serageldin, 2007). Since public research institutes are still the key drivers of basic research in sub-Saharan Africa (Oyelaran-Oyeyinka & Sampath, 2007c), and the private sector is inadequately prepared to commercialize ideas that emerge from these institutes (Lall & Pietrobelli, 2005), public research institutes continue to be important vehicles for developing health solutions in the African context.

These issues are illustrated by the experiences of the Kenya Medical Research Institute (KEMRI). KEMRI is one of Africa’s premier health research institutions, and successfully advised Kenya’s government to withdraw the anti-malaria drugs Chloroquine and Daraprim. KEMRI is also one of the very few research institutes in Africa that has attempted to commercialize its own technologies.

60 WHO. http://www.who.int/mediacentre/factsheets/fs104/en/2010
We used a case study design. Our analysis is based on semi-structured interviews and on-site observations that took place at KEMRI’s Nairobi and Kisumu campuses during the months of June and July 2008, and subsequent visits and interactions over 2008 and 2009 as well as secondary analysis of peer-reviewed literature, articles, news items and web sites. We conducted interviews with informed consent with personnel of KEMRI’s management, product manufacturing facility, scientific staff, and IP management team. Representatives of KEMRI were asked to fact-check the case study; the analysis and interpretation is our own. All quotes are from the interviews unless otherwise noted, and with permission. This study was approved by the Office of Research Ethics of the University of Toronto.

In this article, we explore the role of public research institutes in health product development and commercialization by examining the case of KEMRI. We begin by describing the history of health product development at KEMRI, discuss its successes and challenges, and suggest lessons for policy makers, donors, institutional managers, and African scientists.

5.2.3 Discussion

Context

In 1979, two years after the breakup of the East African Community, the Kenya government established KEMRI as a state parastatal (government-owned organization) to fill the health research void caused by the dissolution of the East African Medical Research Council. Its vision is to be a leading centre of excellence in the promotion of quality health, with a mission of improving the quality of health and human life through research.

Beginning with a staff of five research scientists located in one centre in Nairobi in 1979, KEMRI has now grown to over 450 scientists. KEMRI has attempted to commercialize
its own technologies by constructing a manufacturing facility for diagnostic kits for Hepatitis B (Hepcell) and HIV (Kemcom). Constructed in 2006, the production unit had about 20 employees, out of KEMRI’s total staff population (including non-scientists) in 2009 of roughly 1250. (Note that when we discuss KEMRI’s product development experience in this paper, it is often this production unit and allied units that are key players, as parts of a much larger organization.)

The Institute has two units and eight research centers located in Nairobi, while an additional two centers are located in Kisumu and Kilifi respectively. KEMRI’s most recent ten year strategic plan estimated the annual budget at $37.5 million. The sources of funding are as follows; 50% from the Kenyan government, 45% from collaborating research partners such as major partner Wellcome Trust, and about 5% from internally generated funds that include clinical work, diagnostics, and academic services that KEMRI provides for clients (Teng-Zeng F, 2009). Because of resource limitations, there is pressure on KEMRI to move from a non-profit operational model to one where an increasing share of operations is self-financed.

KEMRI is internationally known for participating in various programs including clinical research, AIDS vaccine development, and conducting clinical trials since 2003 for IAVI (the International AIDS Vaccine Initiative)63. It participated in a pan-African research project (MARA/AMRA) started in 1996 to map malaria risk and endemicity, which led to the development of ‘risk maps’ used in malaria control policy activities and geographical modeling of malaria, enabling the first accurate assessment of the disease burden in Kenya (Chataway et al., 2009). In collaboration with other African research institutes, KEMRI has reportedly also screened thousands of small molecules and natural products against schistosomiasis, malaria, and tuberculosis through the Helminth Drug Initiative, helping provide impetus for the new African Network for Drugs and Diagnostics Innovation (Nwaka et al., 2009).

63 https://www.era.lib.ed.ac.uk/handle/1842/2743
KEMRI’s commercialization initiatives can be traced back to August 24, 1990. On this date, KEMRI announced that it had discovered a cure for HIV/AIDS called KEMRON® (Koech & Obel, 1990). Several groups around the globe that had been involved in developing the product were reported to be jostling for ownership and distribution rights (Patel, 2006). Controversy also arose, with claims that KEMRON® had undergone uncontrolled clinical trials and that further testing would be required to validate its effectiveness\(^\text{64}\). In the US, the case of KEMRON became political with groups alleging that it was a deliberate attempt to stifle African innovation (Anderson, 1992, Highleyman, 1997). While this controversy was raging, a new drug called Immunoplex-N® was patented for the management of AIDS\(^\text{65}\). KEMRI scientists interviewed believed that Immunoplex-N®, now available in numerous countries, has the same molecule as KEMRON®.

According to Dr. James Kimotho, Production Manager, KEMRI, all this happened because the institute lacked experience in innovation management and at that time had no intellectual property policy. The resultant controversy impeded further interest at KEMRI in research commercialization.

**The early years of product development**

The idea to enter product development resurfaced in the late 1990s, prompted mainly by falling budget support by the government and donors, as well as by the desire to make an impact on society by producing health products suitable for local conditions. “Prior to that we were just a typical health research institute focusing on clinical and basic biomedical research,” says Dr. Gerald Mkoji, KEMRI’s Deputy Director. A Centre for


\(^\text{65}\) http://www.medhelp.org/user_journals/show/129138/IMMUNOPLEX-N-for-HEPBC-treatment--HIV-AIDS
Biotechnology, Research and Development was therefore established which was to focus on product development.

Early product development related activities included evaluating products developed in other countries to assess their quality and suitability for the Kenyan market. From KEMRI’s inception, Kenyan health product regulatory authorities like the Kenya Bureau of Standards, the National Public Health Laboratories, and the Pharmacy and Poisons Board would refer some drugs and diagnostics to KEMRI laboratories for evaluation, to determine their safety and efficacy prior to registration on the Kenyan market. According to Dr. Mkoji, KEMRI scientists soon realized that this focus on efficacy and safety was too narrow for effective delivery of health care products to Kenya’s population. Products could be safe and effective, but not suited to meeting local public health challenges – their cost might be too high, or they might require the use of electricity or additional technology that was not readily available in rural areas.

Consequently, according to Dr. Mkoji, KEMRI scientists began researching how to adapt products that had been shown to be effective in other countries, but were not well-suited for local conditions in their existing form. Such research focused initially on diagnostics, though there was also interest in pharmaceutical drugs. In the process, the scientists acquired skills applicable to full product development, including assessing market suitability and requirements.

**Technology Transfer from Japan**

According to our interviewees, the next step towards product development came with the construction of a manufacturing facility. For 25 years, the Japan International Cooperation Agency (JICA) and KEMRI had collaborated in areas of parasitic and infectious disease research. The goal of the collaboration was technology transfer from Japan to Kenya through training and product development. One of the outcomes of this collaboration was the development of diagnostic kits. Prototype blood screening kits were
developed in Japan, and then evaluated at KEMRI and adapted to Kenya. After ten years of product development and evaluation, the partnership led to the development of a Hepatitis B diagnostic kit (Hepcell) for testing blood for transfusion. Hepcell is based on reverse passive haemagglutination technology. This technology was ideal for the Kenyan market, as it was cheaper than transporting blood to laboratories for screening. It was also portable, and could be used in remote environments where there was no electrical power.

For three years, the kits were produced at a small scale in KEMRI’s laboratory using locally available raw materials including cell lines, thus making them cheaper. By 2004, KEMRI had broadened its objectives and began thinking of moving into commercial production by constructing a product manufacturing facility at the institute. “We started thinking of how we could start producing our own innovations and moving products to the market at affordable costs,” says Dr. Wesley Ronoh, marketing manager.

In order to scale up, a US$5-million manufacturing facility was constructed. The decision to manufacture locally instead of licensing out was taken since no local manufacturing facilities existed. The facility was funded with a grant from JICA (the Japan International Cooperation Agency) and additional funding from the Government of Kenya. This state-of-the-art facility opened in 2007 and hosts a current Good Manufacturing Practice (cGMP) certified production unit, laboratories, and offices, all with the goal of pushing diagnostic products to market. The facility is equipped with ultracentrifuges, high capacity centrifuges, a lyophilizer, a precision spraying machine, a precision guillotine machine, a high capacity incubator, and an animal house.

**A white elephant?**

The manufacturing facility was designed to produce two types of diagnostic kits: Hepcell kits for detection of hepatitis B virus, and Kemcom kits for detection of HIV in the blood (both based on particle agglutination technology). However, the management of KEMRI soon realized that there was no institutional mechanism to engage in commercialization
activities. Dr. James Kimotho was then hired as a Production Manager to help the institution manage the facility and its innovations. “We then began to think about intellectual property [and] commercializing innovations, because after putting in place the infrastructure, it became necessary to look and think about moving products to the market at the lowest price and producing our innovations. As a result of that, we set up a marketing office and a technology transfer office, which now began to put in place the necessary institutional policies for commercialization,” says Dr. Ronoh.

But in 2008, KEMRI experienced an unexpected setback: the Kenyan government, a major customer for the diagnostic kits produced at the unit, suddenly stopped purchasing the kits. This was as a result of global World Health Organization (WHO) recommended changes on the screening of blood. WHO recommended use of ELISA based technologies and at the same time discouraged use of particle agglutination based technologies for screening blood in blood transfusion centres. This resulted in blood screening in Kenya moving from using particle agglutination technologies to only ELISA based technologies that were centralized in 5 blood transfusion centres in the country. The health clinics would no longer be supplied with KEMRI’s Hepatitis B and HIV diagnostic kits. In the opinion of Dr. Ronoh, “The institute suddenly found itself with a white elephant – that is, it had expensive and excellent facilities that were not being utilized.”

This setback required a new strategy on how best to use the facility. One approach was to produce point of care diagnostics in the form of rapid Hepatitis B & C and HIV test kits, which are suitable for blood screening and diagnosis. In contrast to KEMRI’s earlier kits, these rapid test kits were based on immunochromatographic technology, and were suitable for adoption as point of care tests. Prior to the development of domestic kits, such kits were imported from Japan, Europe, and other sources by the Ministry of Health. With help from JICA, technology was transferred to KEMRI. KEMRI scientists then developed these rapid test kits, and by late 2008 these new kits were being produced at the facility. However, the facility is still underutilized. The plant’s current annual revenue
is still minimal at about USD $100,000, while its expenses are estimated to be around USD $50,000. According to Dr. Ronoh, the potential market is promising as Kenya requires about 2.4 million HIV rapid test kits a year for use in Voluntary Counselling and Testing centres (VCTs); if the government was to approve the use of these kits, KEMRI could earn at least one million dollars per year.

**Technology assessment and institutional IP policy**

Dr. Ronoh reported that Bridgeworks Africa (a local venture capital firm) was involved in technology assessment of potential products. According to him, the first products were selected on the basis of their market potential, and included a plant extract for multi-drug resistant TB; a plant extract for topical application in the management of Herpes Zoster; a plant extract for treatment of sleeping sickness; and an existing drug used for treating cancer which has shown efficacy against malaria.

The relationship with Bridgeworks was based on a confidentiality and non-disclosure agreement negotiated on a case by case basis with right of first refusal going to Bridgeworks. Dr. Ronoh reported that due to restructuring at Bridgeworks, this process had stalled around 2008, and that KEMRI had its own plans to develop an institutional IP tracking system to track its technologies.

According to Dr. Ronoh, Bridgeworks Africa and the Kenya Intellectual Property Institute (KIPI) assisted in the development of an institutional IP policy, and in establishing relationships which resulted in training programs at international organizations involved in innovation management like the Swedish government innovation agency (VINNOVA) and the Office of Technology Transfer of the NIH in the US. Other relationships were with pharmaceutical companies based in Kenya for product distribution, and with the Kenya Industrial Research and Development Institute (KIRDI) which is Kenya’s national incubator. KEMRI also recruited a legal officer whose duties include negotiating contracts with partners who want to invest in KEMRI products.
**Product diversification**

After the government stopped buying from KEMRI in 2008, KEMRI began to diversify its product portfolio by instituting changes on how to approach commercialization. This was done by opening up activities of the marketing department to other areas instead of focusing only on diagnostics, which resulted in the development of other products.

TBcide® is a standardized chlorine-based decontaminant claimed to prevent occupational exposure when handling Mycobacterium-infected surfaces. According to the scientist who developed TBcide®, it eliminates residual mycobacterium pathogens from surfaces, unlike many conventional disinfectants (Matu et al., 2008); it also has the advantage of being cheaper than imported disinfectants. The product was tested in hospitals in Kenya and patented in 2008 through the Kenya Intellectual Property Institute (KIPI) (Matu, Gitui, & Juma, 2009). In a first for KEMRI, production was outsourced. According to Dr. Ronoh, a private firm has been identified to produce TBcide® and market the product on behalf of KEMRI. He stated that the firm will use KEMRI’s appointed distributor and receive marketing support from KEMRI.

Another product being developed at KEMRI is KEMTAQ, which contains a heat-stable DNA TAQ polymerase that was first isolated from the bacterium Thermus aquaticus but is now produced using DNA recombinant technology. It is used in Polymerase Chain Reaction (PCR) to amplify DNA to adequate quantities that can be handled or quantified easily. DNA TAQ polymerase is a cornerstone of molecular diagnostic techniques. The technology is patented elsewhere but not in Kenya (Chien, Edgar, & Trela, 1976). The process technology for production has been adapted to local conditions using plasmids and E. coli for expressing TAQ polymerase that KEMRI scientists have been able to
reproduce using recombinant technology. It is now being supplied to laboratories in Kenya. All the above products are listed for ordering online from KEMRI 66.

KEMRI scientists are working with traditional healers to develop antimalarials isolated from plants, at KEMRI’s Centre for Traditional Medicine and Drug Research (Kaya, 2009). Dr. Jennifer Orwa, Principal Scientist at KEMRI, indicated that partnerships have been formed with local communities for information and supply of these traditional plant technologies. Memorandums of Understanding have been signed by both traditional healers and institute scientists, which clearly state prior informed consent and benefit sharing.

**Future plans**

According to Dr. Ronoh, KEMRI has been approached for contract manufacturing by domestic and international companies that want to develop health products for low resource settings – reportedly due to its location in a tropical country, and facility availability for trial production of diagnostic technologies. Negotiations are ongoing with several of these organizations to use the facility to produce locally adapted diagnostic kits for the African market.

Dr. Mkoji revealed that one of KEMRI’s potential strategies is to convert the marketing division into an independent enterprise, without abandoning the overall objective of targeting the poor. Additional funding for product development might come from income generating activities of other departments like diagnostic services, clinical services, analytical services, training, and student attachments. Proceeds from these activities would then be used to support innovation. KEMRI plans to retain control—and equity—over products by manufacturing most of them partially or fully in its own production facility.

KEMRI’s marketing department hopes to compete internationally, especially in regional economies, by producing products that can compete globally. “The first step is to get WHO accreditation for our manufacturing facility and products, which we are pursuing,” says Dr. Ronoh. At the same time, KEMRI is trying to influence government policy towards health innovation by recommending to the Kenyan government the need to sensitize implementing officers on the importance of supporting domestic health innovation, by means such as national procurement strategies for suitable health products.

In June 2010, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) reportedly began a business and strategic assessment of the KEMRI Production Facility, to evaluate its procurement potential as a supplier of HIV diagnostics.

We turn now to an analysis of KEMRI’s challenges and business model, and the lessons KEMRI may hold for future development of health solutions in low-resource settings.

5.2.4 Barriers to commercialization

Health product innovation does not occur in isolation, and in sub-Saharan Africa is fraught with many challenges and barriers that arise from within and outside the institution (Chataway et al., 2009). Many of these challenges are a result of weaknesses in the national innovation system of the country.

Our analysis revealed that one major challenge for KEMRI is crossing the “valley of death”: the resource gap between R&D activities and commercialization (Markham, Ward, Aiman, Smith, & Kingon, 2010). The absence of private sector investments in biotechnology and lack of venture capital in Kenya have negatively affected the chances of most of KEMRI’s R&D being commercialized. Dr. Peshu, Director, Centre for

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Geographic Medicine and Research Coast, Kilifi, summarized it as follows, “We have quite a number of products that have shown activity in vitro, in the lab, but now the next stage is to demonstrate more evidence that the products work. The donors are not willing to risk their research grants, for example, for in vivo studies in animals – and then, if this succeeds, to clinical trials. They only support lab studies, so there's a valley of death so to speak.”

The lack of a national policy on health innovation in Kenya was mentioned by interviewees as a factor that has hampered product development and commercialization at KEMRI. The overreliance of the government on donor agencies to fund the Ministry of Health as well as supply it with imported health products does not encourage domestic innovation. The government of Kenya does not protect local innovators from foreign competition, unlike countries like Japan and emerging economies like India and China (Frew et al., 2007; Frew et al., 2008). According to Dr. Ronoh, when approached to purchase from KEMRI, foreign governments (especially those within East Africa) and investors question why the Kenyan government itself is not buying from KEMRI. Part of the problem, says Dr. James Kimotho, “is that the health sector in Kenya is classified in the social pillar and not in the economic pillar in government development policy documents, like Vision 2030”. It is therefore not seen as a potential revenue earner, but as a sector that drains exchequer funds.

Another barrier to product commercialization was the culture of “publish or perish” among scientists. One scientist remarked that promotions were pegged to the number of publications a researcher produced, regardless of their relevance to clinical applications or solving health problems. This has hindered innovation, as researchers focused primarily on basic scientific research. Dr. Ronoh and the staff at the marketing office began efforts to change the mindset of the scientists, with the support of training programs offered by Bridgeworks Africa68. One weakness identified was that local

68 See the Bridgeworks Africa case study from the McLaughlin-Rotman Centre for Global Health.
universities did not incorporate intellectual property knowledge as part of their curriculum for training scientists.

A final barrier mentioned during the interviews is managing intellectual property. Despite KEMRI having its own institutional IP policy and training for scientists, these efforts have been weakened by existing collaborative agreements with research partners that do not adequately address IP issues. According to Dr. Ronoh, research collaboration partners have often maintained clauses entitling them to any IP that comes from a research project that they have funded. In addition, he reports that some KEMRI scientists have negotiated collaborative arrangements with other institutions and groups without paying much attention to IP issues, with the resulting risk that technologies developed from such collaborations may end up in foreign countries without benefiting KEMRI scientists. He says that since the adoption of the institutional IP policy, establishment of the IP office, and recruitment of a legal officer, all collaborative arrangements and agreements are required to include a section that addresses IP issues.

Implicit open innovation business model

KEMRI does not have an explicit business model. However, based on our analysis of the interviews, it appears that the strategy that has evolved to overcome barriers to commercialization closely resembles an open innovation business model (Chesbrough, Vanhaverbeke, & West, 2006). This model assumes that an organization can and should use external ideas as well as internal ideas, and external as well as internal paths to innovation and market – all while trying to advance its technology. If an organization lacks internal product development capabilities, then it can leverage external resources through a combination of strategies. Conversely, an organization can maximize use of its internal production capabilities by attracting innovations and ideas that have been developed outside the organization, and fully developing them.

In the case of KEMRI, this open innovation business model has three aspects:
Linking with investors

From our interviews, the management of the marketing department of KEMRI realized they had limited internal capacity in product commercialization, especially in drug production, and turned to outside organizations for help. KEMRI began exploring outsourcing of some production functions in 2008 with TBcide®, as described above. Dr. Ronoh states that KEMRI staff have conducted a GMP audit of local pharmaceutical manufacturers so that only GMP compliant organizations will be selected as partners to produce products on behalf of KEMRI. The investment from JICA was instrumental in developing the original manufacturing facility for diagnostic kits, and opportunities for contract manufacturing may bring in new investors in the future.

Technology assessment

In order to make good business decisions, it is necessary for an institution to know the potential of the technologies it has. KEMRI pursued technology assessment of potential products in partnership with Bridgeworks Africa. It subsequently formed its own plans to develop an institutional IP tracking system to track its technologies.

Managing IP

As discussed above, KEMRI developed an institutional IP policy and strengthened innovation management capabilities in partnership with a range of external collaborators, both African and international. According to Dr. Kimotho, developing an institutional IP policy is the first step to engaging external investors, and the ability to negotiate licenses and contracts is critical if an institution is to maximize benefits and prevent the theft of IP. He says, “you can't go into product development with naiveté. You will be ripped off.” Interviews with other marketing department personnel indicated that their department aims to ensure that technologies developed are patented before discussions are held with potential investors.

5.2.5 Lessons learned
Our analysis of KEMRI’s experiment with product development suggests several lessons that may be beneficial for other institutions in sub-Saharan Africa that are grappling with similar challenges.

*Investments in research need to be accompanied by investments in innovation management.*

As the case of KEMRI has shown, institutions should develop their own capacity in innovation management. “Inventing is one thing. Taking an invention to market is completely different,” says Dr. Kimotho. Proper integration of innovation management allows organizations to validate the science, establish and integrate technologies, prevent loss of IP, and strengthen business models. KEMRI is developing its capacity in innovation management by sending its staff to participate in local and international training programs.

*Focusing on local markets can generate health benefits, and rapidly create revenue.*

Health products that KEMRI has focused on so far are point-of-care diagnostics, traditional medicines, and disinfectants. Most technologies are customized to address domestic health problems such as malaria, tuberculosis, HIV, and other neglected diseases. Advantages of local technologies include their low cost, convenience, and adaptability to local settings. Both Hepcell and Kemcom were low cost solutions that were portable, cheap, and did not require electricity. This strategy has been a source of revenue and a morale booster to the scientists. Because product development takes a long time and most public research institutes in the developing world face significant shortfalls in finance, it is important to target areas that will quickly bring in revenues that can be ploughed back into new products. These revenues can also be used to purchase more modern equipment that the organization requires, and to demonstrate research impact. If sales of health technologies result in the marketing unit becoming self-sustaining, this may sway policy makers and management to develop favorable policies. KEMRI
management is considering making the production unit autonomous, so that revenues from it do not have to go to the central institutional pool, but instead can be invested back into the facility.

*Proper strategic planning and risk mitigation strategies are critical in volatile business environments.*

The importance of proper planning in product development and the ability to adapt to different scenarios cannot be over-emphasized. Product life cycles can be short. In addition, product development in the developing world occurs in highly uncertain environments (Singer et al., 2007). KEMRI faced near disaster after building its production facility because it implicitly assumed that there would be a guaranteed market. Its experience suggests the value of engaging with relevant regulatory bodies, and the value for both governments and research institutions of supporting strategic local production. Commercialization strategies need to be incorporated when a product is still being researched. Proper planning will ensure that arrangements are in place in case of unforeseen changes, in both technology and markets. Planning includes diversification of the product portfolio: KEMRI diversified from development of diagnostics to development of disinfectants against Mycobacterium and enzymes for DNA amplification.

*Public research institutes should be prepared for a long and difficult process to make health product development work.*

Research institutes must understand that commercialization by public institutes is a complex and difficult process involving many players. While reductions in government funds and fierce competition for donor grants have prompted institutes like KEMRI to look for other sources of revenue, its experience with product development has not been an easy alternative. In addition, the intricacies involved in balancing between a public institute’s social mandate and making profit through developing products can be tricky.
“It is very difficult to produce products for the poor” says Dr. Mkoji. “You have to recover your costs and make some little profit, yet you must make products that are affordable, which is difficult”, he adds. Therefore, institutes need to understand that commercialization is laborious, and they should be prepared to be in it for the long haul.

*Imitation through technology transfer can be the first step to fostering innovation.*

Technological capabilities are critical to product development (Verona, 1999). Local capacity in innovation can be developed through technology transfer, by first establishing facilities that produce variants of products from the developed world. Skills and techniques acquired in these facilities can then be adapted to similar areas. An example of this method of domestic skill development was in Japan where organizations developed their industrial capabilities through imitation of foreign technology and reverse engineering (Hayter & Edgington, 2004). Local production of Hepcell and Kemcom diagnostic kits enabled scientists to acquire skills that could be applied to other diagnostics.

*Research institutes should adopt open business models.*

Literature on technology management shows that organizations have difficulty managing innovations that they have no previous experience developing (Verona, 1999). KEMRI’s strengths include R&D capacity and capabilities in developing diagnostics, but it is weaker in other areas such as drug development. KEMRI has pursued a business model that is closely aligned to an open business model (Chesbrough et al., 2006), whereby it has tried to commercialize its own internal technologies, but sought external linkages and assistance where it lacked capacity. “We have tried to leverage our strengths, especially in diagnostics development, by looking for technologies outside – and tried to use internal mechanisms to develop them” says Dr. Ronoh. To solve local health problems, research institutes need to leverage their strengths while acknowledging their
weaknesses. KEMRI has approached this through linking with investors, outsourcing and licensing, and contract manufacturing.

5.2.6 Summary

This case study of KEMRI reveals the dynamic interaction between institutional factors, external factors, and product development in a public research institute in sub-Saharan Africa. In the early years, KEMRI’s experiment with product development was not very successful, with two key reasons being lack of innovation management experience and lack of an institutional IP policy. Later, KEMRI improved its innovation management and technological capabilities through recruitment and training, but these were still inadequate to ensure the success of its next effort in product development.

Major barriers that KEMRI faced included shifting markets, lack of scientific and production infrastructure, inadequate financing for product development, and weak human capital with respect to innovation. Reliance on a limited set of products, i.e diagnostics, proved to be dangerous as that product line relied on government purchasing. Shortly after construction of a production unit, the government stopped purchasing diagnostics from KEMRI, resulting in an underutilized facility.

KEMRI has since diversified its product portfolio. This has led to limited success in product development, with a portfolio which now includes a disinfectant and rapid HIV and Hepatitis B test kits. Given the weakness of internal capabilities in some areas of product development, KEMRI has adopted an open innovation business model which includes partnerships with other firms. Internal changes have also been instituted, including development of an institutional IP policy and programs promoting a culture of innovation among scientists.

Lessons were identified in the study that could have implications for other research institutes in sub-Saharan Africa seeking to develop health products. These lessons
include: investments in research need to be accompanied by investments in innovation management; institutions may wish to initially focus on local markets to generate immediate health and financial benefits; a volatile business environment in Africa implies a need for proper strategic planning; and open business models can help institutions leverage outside strengths to develop products. Expert demand analysis and forecasting is also critical.

KEMRI’s experience shows that with the right policies, challenges to product development are not insurmountable. Research institutes in Africa can turn science into health solutions for local health problems, thus reducing Africa’s health burden.

Figure 4: History of product commercialization at KEMRI

1973: East African Medical Research Institute established (EAMRI)
1979: Kenya Medical Research Institute is formed following dissolution of EAMRI
1990: KEMRON controversy
1998: Japanese International Cooperation Agency (JICA) with KEMRI scientists begins research into diagnostic kits
2005: Construction of production facility for point of care diagnostics begins
2006: Linkage with Bridgeworks Africa to develop institutional IP policy
2007: Completion of production facility
2008: Launch of TBcide, a chlorine-based decontaminant for handling Mycobacterium.
Chapter Six: RESULTS: TECHNOLOGY LEVEL CASE STUDIES

6.1 Introduction

This chapter discusses the results of study 3, the case studies at technology level, by reproducing in full, a manuscript published in Science journal.

The chapter relates to specific objective 3). Technology level. The objective of this part of the study was to describe and analyze health technologies that may exist in Sub-Saharan Africa’s health research institutions but are not being commercialized. These technologies are referred to here as stagnant technologies. The questions were:

a) What types of stagnant technologies are being developed in Africa’s research institutions including their uses and applications and technological opportunity (which include such variables as performance, cost, standards, institutional culture and other external variables).

b) What are the barriers and challenges scientists in Africa face in their attempt to commercialize these technologies?

c) What strategies can be adopted to commercialize these technologies?
6.2 Stagnant Health Technologies in Africa

Previously published as:


Authors' contributions
Ken Simiyu, Abdallah S. Daar and Peter A Singer contributed to the concept and design of this study, participated in site visits, analyzed the findings, and participated in manuscript development.
6.2.1 Summary

Commercializing stagnant health technologies may help alleviate some of Africa’s health and economic problems.

6.2.2 Introduction

In Madina village, outside Accra, Ghana, children tease each other to see whose urine has a redder color than their friends. Apart from being strikingly thin, they look healthy. Yet they could be affected by Schistosoma haematobium (Daar & Scrimgeour, 2000), a parasitic disease common in Africa, where local prevalence rates can exceed 50% (Hotez & Fenwick, 2009). Early diagnosis ensures inexpensive and effective treatment, and prevents stunted growth and developmental disabilities in children and bladder cancer or other organ damage in adults (Andrade, 2009). But the standard method of detecting the disease, microscopic identification of eggs in urine or stool, requires patients to visit a hospital laboratory, something not practical for many people living in rural Ghana.

The solution could be just twenty kilometers away, at the Noguchi Memorial Institute for Medical Research in Accra, where a low cost point-of-care rapid monoclonal antibody-based dipstick technology has been developed to diagnose the disease. This visually-read test can be used at the village level. Although this work has been published (Bosompem, Owusu, Okanla, & Kojima, 2004), the technology, which has the potential to save lives in Madina, has not been commercialized; instead, it lies stagnant.

Unfortunately, this situation is replicated in many of sub-Saharan Africa’s health research institutions where many technologies are being researched but not commercialized; that is, converted to a product or service that generates profits or has an impact on the everyday lives of Africans (Gans & Stern, 2003).
To better understand why this is happening, 23 academic and health research institutes were visited in Ghana, Kenya, Nigeria, Rwanda, Tanzania and Uganda and interviewed 39 scientists about technologies they were developing and reasons that these technologies were stagnating (see chapter 3 for a full description of study methodology). We consider technologies stagnant if they still need testing and validating or if they have been validated but are not adequately commercialized. We discuss here some approaches to these problems. Previous studies in Africa have examined health innovation at country level (Banji, 2007), but to our knowledge there are no systematic studies of stagnant health technologies. This article, therefore, highlights some of these technologies and why they stagnate, as described by the African researchers themselves.

6.2.3 Examples of stagnant technologies

We identified 25 technologies including traditional plant products, new drug molecules, diagnostics, vaccines and medical devices (see table 5 below).

Many of the technologies identified (16/25) were products of traditional plant medicines. Examples include an anti-malarial product, Nibima, from a traditional plant *Cryptolepis sanguinolenta* (Mills-Robertson, Aboagye, Duker-Eshun, Kaminta, & Agbeve, 2009), which is being developed by scientists at the Centre for Scientific Research into Plant Medicines, in Mampong, Ghana; and Sunguprot in Kenya from the plant *Tylosema Fassoglensis*, whose developers claim can be used to manage HIV symptoms (Mecham, Otieno, Palchinsk, & Fernendes, 2007). Lack of advanced scientific equipment to isolate compounds or funds to carry out clinical trials have affected further development and validation.

Researchers at Tanzania’s National Institute of Medical Research are working on alternative methodology to extract and purify artemisinin from *Artemisia annua* and prepare derivatives or combine it with other anti-malarials to combat the emerging problem of artemisinin resistance. But they lack a larger machine to produce enough extract to carry out clinical trials and facilities for structural analysis of drug molecules.
Other scientists are working on developing point-of-care diagnostics. At the University of Ghana, researchers are developing a visually-readable portable dipstick test that uses monoclonal antibodies to detect the malaria parasite in urine. Work at Makerere University in Uganda focuses on developing a rapid diagnostic test for XDR-TB. But the focus has not been on commercialization. As one of the scientists we interviewed said, “I have developed this rapid-detection test which has shown positive results in the lab but my motive was never to develop a product.”

Scientists are also developing medical devices and equipment. Notable ones identified in this study include a fuel-free medical-waste incinerator, developed at Makerere University, which is cheap to purchase and operate, portable, and suitable for use in rural settings. This could provide a solution to management of hospital waste in rural areas, especially for programs such as mass polio immunization. At the International Centre for Insect Physiology and Ecology in Kenya, researchers have patented human odors that are effective in repelling mosquitoes. However, there is need for further research to determine formulations though negotiations are ongoing with a multinational company.

The above are just a few highlights of the stagnant technologies identified, which are at different stages of development. They may not be representative of every institution and country in Africa, but they serve to illustrate the scope and extent of technology stagnation in sub-Saharan Africa.

6.2.4 Why do technologies stagnate in Africa?

While bringing technologies from lab to village faces scientific, ethical, commercial, and political barriers (P. A. Singer et al., 2007), our focus here is on barriers to developing validated commercial products.
Among the key reasons why technologies stagnate is the cultural mindset of scientists and domestic and international policy makers whose focus is not commercialization. Like in the rest of the world, academic researchers are typically judged by publications rather than economic impact or lives saved, but this problem is particularly vexing in Africa because the health needs are so great. As one scientist put it “My primary focus is to teach and publish. Someone else can take up products to develop them if they are interested as no one will recognize my effort.”

Lack of institutional mechanisms to support further validation and subsequent commercialization exacerbates the problem. For example, there are few innovation funds such as the millennium fund in Uganda and the Innovation fund in Kenya to support proof of concept and prototype development. Because of the inherent uncertainty of life sciences most of the funds end up going to fields like engineering. Venture capital is not available. While there have been funding pledges – for example in 2007 African union Heads of State committed to devoting 1% of their GDP to science and technology - these commitments have rarely been met.

Other barriers identified by researchers included: poor government and institutional policies to support commercialization, inadequate or poorly understood intellectual property regimes, regulatory bureaucracy, and user perception favoring foreign products.

6.2.5 Commercializing stagnant technologies

Why is it important to commercialize stagnant technologies? Because turning creative ideas, particularly those of young people, into goods and services that meet market needs is how economies grow. Indeed, other than the non-corrupt exploitation of natural resources, it’s the

main way countries develop. It is what happened in South Korea, what is happening in India, China and Brazil, and what will inevitably happen in Africa.

Unlike in developed countries, product development and commercialization in Africa at present involves local improvements of technologies developed elsewhere; modifying imported technologies to suit local conditions (usually focused on cost reduction); or less commonly, novel product development (Aubert, 2005). While commercialization challenges remain in countries like China, India and Brazil, the situation there is improving (Frew et al., 2007; Frew et al., 2008; Rezaie, Frew, Sammut, Maliakkal, Daar, & Singer, 2008) and those countries’ products will provide stiff competition for African products. The immediate objective of product commercialization in Africa is not to replace globally known effective technologies or compete with them, but to increase their accessibility through adaptation and cost reduction. But in the long term, once the commercialization culture has been embedded, hopefully Africa could compete more effectively with the rest of the world.

In every country, there will be researchers, healers, or entrepreneurs claiming they have developed remedies or technologies that work. But when subjected to rigorous testing and evaluation in clinical trials many do not work. Some believe the only immediate priority should be infrastructure and expertise development to rapidly field-test technologies to determine which ones are worthy of commercialization (Scott, 2007). We believe, however, that validation and more downstream commercialization activities – including regulation to ensure bad technologies are kept off the market – should be pursued in parallel to link innovation to the market and consumer needs.

Several health product development and commercialization initiatives are underway in Africa: the African Network for Drugs and Diagnostics Innovation (ANDI) which aims to enhance innovation in Africa by strengthening intra-African research collaboration (Nwaka et al., 2010); product development public-private partnerships, for example one that led to a meningitis vaccine (Hotez & Brown, 2009); and the U.S. President’s Emergency Plan for
AIDS Relief investment model of enabling its contractors in Africa to attract private capital. However, none of these is focused on the pipeline of stagnant technologies.

From our previous work in Kenya, Uganda, Rwanda, Ghana and Tanzania, three important needs emerged: proof-of-concept funds, virtual networks linking scientists and entrepreneurs, and physical centres providing shared research infrastructure (P. Singer et al., 2008). One initiative to address these needs and promote product commercialization in Africa is the establishment of Life Sciences Convergence Innovation Centers (Masum, Daar, Al-Bader, Shah, & Singer, 2007). These proposed centers would bring together science, business and capital, and serve as “one stop shops” for private investors who wish to tap into the pipeline of domestic African technologies and support an entrepreneurial approach to innovation in Africa.

One specific proposal that emerged from a conference we organized in February, 2010 for science policy makers from East Africa in Nairobi, Kenya was the creation of a Bioscience East African Angel Network (i.e a group of private individuals willing to risk their capital on early stage R & D). While still a concept at present, the need for private capital was clearly felt. Other than Bioventures, a venture fund in South Africa, we are unaware of any functioning venture capital fund in life sciences and health in sub-Saharan Africa. What is clearly needed is a venture fund to provide capital to promising ideas, like some of those we have identified, which are currently stagnating in research institutions. The fund could be shaped by lessons learned from venture funds in India (APIDC), China (Bioveda) and South Africa (Bioventures), which include drawing the right mix between for-profit investments and social impact.

An African venture capital fund for science based health innovation would make a huge difference, not only because of the money but also the mentorship and management experience that is brought to bear through the investments. The Convergence Centre-VC fund platform could also be applied to other innovative sectors. The unlocked potential may
create new opportunities, providing a pathway to prosperity, jobs and better health. This is the next big step in global health.

Table 5: The scope and extent of health technology stagnation in sub-Saharan Africa

<table>
<thead>
<tr>
<th>Technology</th>
<th>Description of technology (according to the scientist)*</th>
<th>Health area of application</th>
<th>Country/Institution</th>
<th>Status (according to the scientist)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Traditional plant medicines</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Artemisinin/lemon grass combination</td>
<td>A beverage that is used to treat malaria</td>
<td>Malaria</td>
<td>Uganda- Natural Chemotherapeutics Research Laboratory</td>
<td>Ready for commercialization, but not yet commercialized. Undergoing clinical trials in northern Uganda</td>
</tr>
<tr>
<td>2. Nibima- Extract of traditional plant Cryptolepis sanguinolenta</td>
<td>Whole plant extract for the management of Malaria</td>
<td>Malaria</td>
<td>Centre for Scientific Research into Plant Medicine, Mampong, Ghana <a href="http://www.asnapp.org/">http://www.asnapp.org/</a></td>
<td>Needs validation through clinical trials</td>
</tr>
<tr>
<td>10. Whole plant extract</td>
<td>Treatment of Fibroids in women</td>
<td>Fibroids</td>
<td>Kenya- Moi University <a href="http://www.mu.ac.ke/">http://www.mu.ac.ke/</a></td>
<td>It is undergoing tests in humans in the form of pill formulations (Phase 1 clinical trials)</td>
</tr>
<tr>
<td>11. Whole plant extract</td>
<td>Has anti-sickling properties which are attributed to its ability to prolong or delay the time</td>
<td>Sickle cell anemia management</td>
<td>Nigeria-NIPRID <a href="http://www.niprd.org/">http://www.niprd.org/</a></td>
<td>Orphan drug status by the US Food and Drug Administration (FDA) and the European Medicine Evaluation Agency</td>
</tr>
<tr>
<td>No.</td>
<td>Product/Technology</td>
<td>Description</td>
<td>Application</td>
<td>Technology Provider</td>
</tr>
<tr>
<td>-----</td>
<td>--------------------</td>
<td>-------------</td>
<td>-------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>12</td>
<td>Anti-Hepatocyte</td>
<td>Plant derivative-A treatment of liver infections especially liver cirrhosis</td>
<td>Liver ailments</td>
<td>Tanzania-NIMR</td>
</tr>
<tr>
<td>13</td>
<td>Aloe vera derivatives</td>
<td>Skin ointment</td>
<td>Skin ailments</td>
<td>Tanzania –MUHAS</td>
</tr>
<tr>
<td>14</td>
<td>Aloe vera derivatives</td>
<td>Skin ointment</td>
<td>Skin ailments</td>
<td>Rwanda-IRST</td>
</tr>
<tr>
<td>15</td>
<td>Plant extract</td>
<td>Prevents the effects of radiation during x-ray’s hence preventing cancers</td>
<td>Anti-radiation</td>
<td>Nigeria-University of Ibadan</td>
</tr>
<tr>
<td>16</td>
<td>Mondia Tonic</td>
<td>Root of <em>mondia whytei</em></td>
<td>Anti-depressant</td>
<td>Kenya-ICIPE</td>
</tr>
<tr>
<td>17</td>
<td>Monoclonal antibody test for detection of malaria</td>
<td>A dipstick that uses antibody antigen reactions to detect presence of malaria parasites in the body by testing urine</td>
<td>Malaria</td>
<td>Ghana-University of Ghana</td>
</tr>
<tr>
<td>18</td>
<td>Monoclonal antibody test for Schistosomiasis</td>
<td>Rapid visually read monoclonal antibody (MoAb) based dipstick</td>
<td>Schistosomiasis</td>
<td>Ghana- Noguchi Memorial Institute for Medical Research</td>
</tr>
<tr>
<td>19</td>
<td>ELISA</td>
<td>A quick test for identifying MDR TB in spitum</td>
<td>Tuberculosis</td>
<td>Uganda-Makerere University</td>
</tr>
<tr>
<td>20</td>
<td>Medical waste incinerator</td>
<td>A fuel free medical waste incinerator. Suitable for destruction of plastics. Uses medical waste as fuel by generating very hot gases</td>
<td>Medical waste</td>
<td>Uganda-Makerere University</td>
</tr>
<tr>
<td>21</td>
<td>Female sanitary towels</td>
<td>Sanitary towels developed from lemon grass. Cost ⅓ of conventional sanitary towels and suitable for school girls</td>
<td>Sanitary towels</td>
<td>Uganda-Makerere University</td>
</tr>
<tr>
<td>22</td>
<td>Insect repellant</td>
<td>Use of human odors to repel malaria causing mosquitoes</td>
<td>Malaria</td>
<td>Kenya-ICIPE</td>
</tr>
<tr>
<td>23</td>
<td>Insect repellant</td>
<td>Plant extract</td>
<td>Malaria</td>
<td>Tanzania-NIMR</td>
</tr>
<tr>
<td>24</td>
<td>TBCide.</td>
<td>Disinfectant. Standardized chlorine based decontaminant used to destroy MDR TB</td>
<td>Tuberculosis. resistant bacteria on surfaces bacteria from hospital surfaces</td>
<td>Kenya-KEMRI</td>
</tr>
<tr>
<td>25</td>
<td>Alternative methodology to extract and purify Artemisinin</td>
<td>To prepare derivatives or combine it with other anti-malarials to combat Artemisinin resistance</td>
<td>Malaria</td>
<td>Tanzania-NIMR</td>
</tr>
</tbody>
</table>

* Scientists interviewed were asked not to disclose any potentially proprietary information.
Chapter Seven: DISCUSSION AND CONCLUSION

7.1 Introduction

This thesis contributes to the literature on health production commercialization in Africa by investigating *opportunities and challenges that exist at national, institutional and technological level towards commercialization of science based health technologies*. Three different studies were conducted using case studies at each of the levels. The concept of innovation, which is central to health product commercialization, was explored from case study specific experiences.

The research was spurred by the void in literature on this subject. While there is literature on health innovation in emerging economies e.g India, and China (Frew, Kettler, & Singer, 2008), Brazil (Rezaie, Frew, Sammut, Maliakkal, Daar, & Singer, 2008) and Cuba (Thorsteinsdóttir, Sáenz, Quach, Daar, & Singer, 2004), the literature does not reveal any in-depth country case studies on science based health innovation in Africa. Most of what has been done in Africa has been limited country surveys of the overall innovation system; thus, the phenomenon of science based health innovation is poorly understood in the African context.

Chapter 2 identified some of these voids in the literature on health product commercialization in Africa which included; limited empirical information on health innovation in Africa; limited literature on commercialization strategies of Public Research Organization’s in Africa and; limited documentation of health technologies available in Africa.

Chapters 4, 5 and 6 discuss the results of the three case studies. Each of these result chapters includes its own discussion and conclusion section hence they will not be reproduced in this chapter. Rather a summary of the main findings will be presented and the broader implications for health innovation in Africa discussed.
7.2 Study limitations

While this chapter offers several empirical and practical contributions of this thesis, there are a number of limitations. The first limitation is that this study used the national innovations framework as the theoretical framework to study innovation in Africa. This framework was used to identify and define the various actors involved in health product commercialization in Africa.

The applicability of the National innovation system theoretical framework to study innovation in developing countries, and in particular, in African countries, is yet to be understood. Indeed, several authors e.g Erbil, (2007), Mani (2004), Dantas (2005), Ahrens (2005), Lall & Pietrobelli (2003) etc have discussed the difficulties of applying the NIS to developing countries (Ahrens, 2005; Dantas, 2005; Erbil, 2007; Lall & Pietrobelli, 2003; Mani & Romijn, 2004a; Mani & Romijn, 2004a; Mani & Romijn, 2004b). Their main argument is that external factors greatly affect a government’s ability to execute autonomous policies. There is also still no consensus by authors on what constitutes innovation in the African context (Aubert, 2005; Edquist, 2005; Frew, Kettler, & Singer, 2008; Oyelaran-Oyeyinka, 2006) or whether the innovation systems approach can be used to prescribe development approaches by African countries just as it has been used to explain economic development in emerging economies like China and India. These are areas that still need further research.

The second limitation of this thesis concerns the generalizability of the study findings to other cases based on the present case study methodology. Scholars have questioned the extent and nature of generalizability of case studies (Hillebrand, Kok, & Biemans, 2001). The intention of this study was to study health product commercialization phenomenon in detail in particular settings. It did not have the intention of generalizing the situation to other countries but rather provide them with lessons. Care should be taken in
extrapolating these results to others as each country and institution has its unique cultural and environmental variables that influence commercialization.

Regarding the stagnant technology study, this section relied only on the views of the scientists involved. There was risk of bias as scientists might want to show that their technology is well developed and can actually do as they claim, yet they may not have any scientific proof. Thus, further work is needed in more countries and more research institutions in order to ascertain the role that various actors play in innovation in their countries. Such research could determine whether indeed results can be generalized. Indeed, there should be studies on health innovation systems of all fifty three African countries.

Similarly, the study of stagnant technologies relied on purposive sampling to identify scientists who may be developing technologies. Purposive samples may not be representative of populations as there is likelihood that only technologies from well known institutions and scientists were studied. But the findings of this study can be used as preliminary data that acts as a foundation to carry out a full scale technological audit and documentation of all available technologies in Africa with the potential for commercialization.

Notwithstanding these limitations, these study offer useful findings and recommendations as detailed below.

7.3 Summary of main findings

The main findings of this thesis are summarized under each study and then a synthesis of commonalities and differences across the three studies is provided.

7.3.1 National level
The results and conclusions of this case at the national level are discussed in Chapter 4 of this thesis. The purpose of the study was to describe and analyze health innovation and biotechnology at the national level. The main objective was to understand the actors, and the system, highlighting its strengths and identifying its weakness. Below are the research sub-questions used to address this question:

a) What is the role of government as a facilitator and policy formulator in the system of health innovation?

The case study of Rwanda provided an insight on how governments in Africa can influence health product commercialization. African governments can do this by creating explicit policy documents like the science, technology and innovation policy that Rwanda passed. Rwanda also has a health policy document that prioritizes areas of health that the government wants to focus on, including supporting health R & D. In addition, the government has carried out explicit policies aimed at increasing R & D by increasing R & D expenditure to 1% of its GDP. Similarly, investments in all levels of education have increased the knowledge base by increasing student enrolments in institutions of learning.

b) What is the capacity of the country’s health research institutions for creating and undertaking research and development (R & D)?

Chapter 4 showed that the many of Rwanda’s research institutes have poorly developed scientific infrastructure. Most of these are public research institutes and include Institut des Sciences Agronomiques du Rwanda (ISAR), Institute of Scientific and Technological Research (IRST) and National University of Rwanda. As the study has shown, most of the infrastructure at the country’s leading scientific institution, ISAR, was destroyed during the 1994 war. Similarly, infrastructure at other institutions including NUR and IRST requires upgrading. Additionally, there is also a shortage of skilled personnel as a result of brain drain whereby scientists have moved to organizations within Rwanda that do not conduct research such as NGOs, which both tend to offer better working conditions while others have moved abroad.
c) **What is the capacity and sustainability of the private sector to acquire and utilize local R & D outputs?**

For successful health product commercialization to take place there is need for a vibrant private sector (Breschi et al., 1997). Chapter 4 shows that the private sector in Rwanda is still nascent and as such does not have an active R &D component. This weakness in the private sector also means that it is not capable of tapping into the products that may be produced by the research organizations.

d) **What is the role of foreign donors and international organizations in innovation in countries?**

The results from the Rwanda case study show that foreign donors play a key role in Rwanda’s health product innovation. The study showed that about 60% of Rwanda’s budget is funded by donor countries. In addition, specific science and technology funding is being undertaken by organizations like DFID, the World Bank and AFDB. Most of this support is through sectoral support of government activities in STI but there is also direct project support in research institutions. There are also collaborative activities with many institutions in the west, such as Carnegie Mellon in the US. Research orientation at the research institutes is mainly dependent on donor priorities. This has hampered a lot of innovative thinking as scientists cannot prioritize their own research.

e) **What are their linkages/interactions between actors in the system of innovation?**

One of the major weaknesses that this study identified is that there are very limited linkages between actors in Rwanda’s national innovation system. As evidence from the case study shows, scientists in Rwanda working in different institutions barely know each other; they have no idea of who the main private sector players are; the private sector does not know what innovative capacity or products exist in the country’s research institutions and there is no information flow to policy makers. In summary, a crucial component of the innovation system is missing, i.e knowledge flow between various actors.
In summary, Rwanda is a late bloomer in science-based health innovation and biotechnology, mainly because of events preceding and during the 1994 genocide. There is very little innovative activity occurring in the institutions or in the private sector. The number of scientists is still very low, and even those who are present are not generally motivated to carry out innovation.

However, because Rwanda is still at an early stage in developing its institutions, it is well positioned to shape its institutions in line with current challenges in science-based health innovation and biotechnology; its institutions are not bogged down by the bureaucracy and rigidity that characterize many more-established institutions in Africa. Many of the staff in the institutions are young and amenable to change, and could easily embrace innovation if properly motivated. In addition, the country enjoys enormous goodwill among the donor community to implement many initiatives that the government proposes. It also has a large pool of skilled people in the diaspora who are willing to contribute towards developing their homeland. Building on these assets and strong political commitment, Rwanda has the potential to make effective use of science-based health innovation.

7.3.2 Institutional level

Chapter 5 of this thesis dealt with the study of health product commercialization at the institutional level. The unit of analysis was a public health research institution in Kenya, KEMRI. The main research aim was to analyze the commercialization environment, including the challenges as well as the microeconomic and strategic conditions that the health research institution is facing in its attempts to translate ideas and technologies into products.

The sub-questions used to address this were as follows:

a) What is the organizational structure?
As a public research institution, KEMRI is mandated to carry out specific activities on behalf of the government, including but not exclusive to the improvement of the social welfare of the people. KEMRI is run by a CEO who answers to the Board of Directors.

b) What is the institution’s research and development (R & D) capacity including examples of products being developed?

Results show that KEMRI has scientific capacity in R & D. KEMRI established a 5 million dollar production facility to facilitate commercialization of its innovations. The facility was first established to develop diagnostic kits for HIV and Hepatitis and later a marketing division was established that looked at broader areas that could form the basis of fully fledged commercialization activities. Thus, KEMRI has been able to successfully develop and commercialize several products including detergents and laboratory products. However, there are still limitations in commercialization especially of traditional plant products. Part of this limitation is due to lack of advanced scientific equipment for structural analysis like NMR’s.

c) What is the organization policy towards Intellectual Property (IP)?

The results show that KEMRI has developed an Institutional IP policy that shows how benefits are shared between scientists and the institute. At the same time there have been activities towards encouraging scientists to learn about IP and to be able to identify if their technologies are patentable or if components of their technologies are patentable.

d) What strategies has the institution adopted regarding technology transfer either within the institution or eternally?

From the case study, the results show that KEMRI has adopted an implicit open innovation business model in its attempt to commercialize its research. In this model, organisations use external ideas as well as internal ideas, and internal and external paths to market, as they look to advance their technologies (Chesbrough, 2003). Thus KEMRI has developed relationships with several external partners to assist the organization in
developing products. Similarly, the institution is open to assist external individuals and organizations commercialize their innovations.

e) What are the challenges and barriers that hinder effective technology transfer?
The case study identified several challenges that KEMRI faced in its attempt to commercialize its research findings. Among the main challenges is that KEMRI relied on only one major product whose market was very volatile. The initial products were HIV and Hepatitis test kits, with the Ministry of Health in the government of Kenya as the main purchaser. However, when WHO changed regulations requiring that the screening of blood changes from point of care to an automated system, KEMRI had no market for its kits and they were no longer needed. Other challenges include cultural ones whereby scientists are evaluated based on publications rather than lives saved and poor IP knowledge. Health product development at KEMRI is also affected by the overall government policy that does not favour innovation. In order to overcome this, KEMRI’s marketing team started to develop rapid diagnostic kits that is used for limited blood testing for experimental work.

In summary, KEMRI faced many challenges in its attempt at health product development, including shifting markets, lack of infrastructure, inadequate financing, and weak human capital with respect to innovation. However, it overcame them through diversification, partnerships and changes in culture. The findings could have implications for other research institutes in Sub-Saharan Africa seeking to develop health products. Such institutes must do demand analysis, yet be prepared to face the unexpected and develop appropriate risk-mitigating strategies.

7.3.3 Technology level

This was addressed by looking at case studies of technologies being developed in several African institutions. The results are discussed in detail in chapter 6. The objective of this part of the study was to describe and analyze health technologies that may exist in Sub-
Saharan Africa’s health research institutions but are not being commercialized. These technologies are referred to here as stagnant technologies.

The sub-questions were:

a) What types of stagnant technologies are being developed in Africa’s research institutions including their uses and applications and technological opportunity?

From the results, 25 technologies including traditional plant products, new drug molecules, diagnostics, vaccines and medical devices were identified. The majority of the technologies identified (16/25) were products of traditional plant medicines. They were also mainly being developed to combat local ailments including common tropical diseases like malaria, HIV management, Tuberculosis, skin and cough infections and cancers.

Analysis of some of these technologies shows that they are low cost applications, designed to overcome common barriers to their effectiveness. For example, in the area of diagnostics, African scientists are trying to develop point-of-care diagnostics that do not require sophisticated application of technical skills or do not require invasive procedures including drawing of blood. Scientists are also trying to overcome challenges of poor availability of electricity by developing diagnostic tests that do not require use of electricity.

b) What are the barriers and challenges scientists in Africa face in their attempt to commercialize these technologies?

Despite promising attempts to develop technologies, scientists face many barriers. Many of the technologies identified need further validation hence there is need for investment in scientific infrastructure. Other barriers include cultural mindset of the institutional management and scientists. Research excellence is still pegged to academic publications rather than number of lives saved. In addition there is significant lack of risk capital to move products from the basic research stage, to proof of concept. Other general
challenges include poor knowledge of intellectual property management and lack of entrepreneurial skills among scientists.

c) What strategies can be adopted to commercialize these technologies?
From the results, one area that was proposed is the establishment of an innovation centre as well as an African venture capital fund for science based health innovation. This would make a huge difference, not only because of the money it would inject into businesses and technologies, but also the mentorship and management experience that is brought to bear through the investments.

In summary, there are many technologies being developed by African scientists. These technologies have been developed to take into account the context in which they will be applied. In addition, they are centered on cost reduction. However many of them have stagnated in the laboratory, as a result of a lack of risk capital to further develop them to proof of concept stage, among other things.

7.4 Synthesis of findings across the three levels

The synthesis of the answers to the sub-questions now enables us to answer the main research question. The general research question that guided this study is “what are the opportunities and challenges that exist in Africa at National, Institutional and technological level towards commercialization of science based health technologies?”

All three studies have identified several opportunities for commercialization of science based health technologies in Africa. These opportunities range from traditional plant medicines, vaccines, diagnostics, and medical devices. Chief among them is the area of traditional plant medicines. Every country is rich in its own plant medicines and these have been used for long periods of time to treat common human ailments. Thus, they are a good source of lead products for new drugs. In addition, African scientists are developing vaccines, medical devices and diagnostics that take into account the local
context, which can go a long way in overcoming some of the challenges to delivery of health products to those who need them the most. As has been found in previous studies on health product development in developing countries (Frew et al, 2007), cost reduction is central to health product commercialization in Africa.

Similarly, these studies identified factors that create an enabling environment for commercialization to take place. Among these factors is a supportive political environment. This also affects how institutions orient their activities and encourages creativity of scientists.

The three studies have identified several challenges common across national, institutional and technology levels that can promote health product commercialization. Many of these challenges are similar to those that hinder innovation elsewhere in the world but they are amplified in Africa because of other issues, chief among them lack of supporting infrastructure include intermittent supply of electricity, poor telecommunication and internet services, lack of appropriate scientific equipment and limited or absent IP regimes. In addition, the issue of bad governance and corruption still persists in many African countries and institutions and imposes severe limitations on the potential of institution’s to innovate.

One challenge that was identified across all three levels to various degrees is lack of funding. At national level, lack of funding hinders the development of a strong scientific community who are essential for commercialization activities to be carried out. This is usually due to different budget priorities by governments. Funding is required at all academic levels from high schools to tertiary education institutions. Lack of funding limits the number of students undergoing masters and PhD level training yet they are the foundation of research activities. In addition there is limited funding for short term specialized training. However, this lack of funding was not so pronounced at institutional level perhaps because the institution chosen for this study was the premier health research institution in Kenya and therefore has well trained scientific staff. But at technology level
there were some scientists who indicated that they need specialized training, usually short-term, in some technical areas; for example some aspects of molecular biology techniques.

Lack of strong domestic markets also affects commercialization at all three levels. In Africa, the government is the main provider of health services hence the main source of health products. If the government does not procure locally produced products then innovators of health products in the country in general have very little incentive to develop products because sales is the main source of revenue that can be ploughed back to encourage further innovation. In addition it acts as a reward system for hard work. Lack of government procurement affects institutional and technology level innovation as most of the products being produced are targeting diseases of the poor. If the government does not purchase them, at least for a start, then they will not be able to penetrate the market.

Poor regulatory policies also affect all three levels because these determine the market for the products. Health products are highly regulated as they have an impact on the human body. Having regulations in place that make it easy for locally developed high quality products to be registered and marketed while restricting the importation of sub-standard foreign products also acts as a way of incentivizing domestic innovation. Since most of the technologies identified are done within institutions getting approval to market the products should not be difficult if national regulatory authorities have the capacity and expertise to handle approval requests.

Another common challenge at the three levels is the cultural mindset. At the national level policy makers have not internalized health product commercialization as a way of national economic development. They instead still consider health as a social service. Yet commercialization of health products can create jobs, save foreign exchange from importation of health products and potentially can be a source of revenue through exports. The management of research institutions has also not considered innovation as a
potential source of revenue for institutions. This has affected the establishment of the necessary policies that would encourage commercialization. Because scientific excellence is pegged on publications the study found that individual scientists do not follow-up on their publications by commercializing their ideas.

The findings of this study are similar with those of Oyelaran-Oyeyinka (2007) who found systemic weaknesses in the innovation systems of Kenya, Tanzania and Uganda (Oyelaran-Oyeyinka & Sampath, 2007a). However, Oyelaran’s case studies involved surveys of the entire innovation systems in general of these countries. In these studies, there is no focus on health innovation and is instead dominated by innovation in other fields especially agriculture and engineering. Actors involved in health innovation including health research institutions and health policy makers have not been fully analyzed in Oyelaran’s study.

In summary, commercialization of health products from sub-Saharan Africa presents opportunities to solve some of Africa’s health problems. In addition to health benefits, commercialization can also lead to economic returns from both domestic and export markets as well as create jobs for people in Africa. This research raises the profile of indigenous African innovation that will help to challenge the idea that innovation only occurs at the technological frontier of rich economies. In turn, this can help African countries and, in particular, the private sector within African countries, to establish fruitful partnerships with local and international groups to build capacity and tap into the new sources of knowledge and know-how so important for growth.

7.4.1 Contributions of the thesis to the literature

This study offers several empirical contributions to the literature on health product commercialization in Africa. First, previous country studies have mainly been general
country innovation system surveys (Oyelaran-Oyeyinka & Sampath, 2007a) with no in-depth case studies on the subject of health product commercialization in African countries. At the same time there are no studies on commercialization strategies of health research institutions and on the availability of health technologies that potentially could be commercialized.

Adopting a qualitative approach and a research strategy of first-hand field research, description and interpretation ensures that the richness of a case is captured. This approach enabled us to look in-depth at factors that affect health product commercialization at national, institutional and technological levels; details that other methods e.g, surveys, may not be able to tell. In particular, because of this approach, this study was able to identify why there are missing linkages and lack of knowledge flows between various actors that are involved in the innovation process. Secondly, the use of interviews enabled us to understand, from the African scientists themselves their own experiences, thoughts and suggestions towards health product commercialization.

Thus the Rwanda and KEMRI case studies in this thesis fill a void in the literature at the institutional and technology levels respectively. Lessons from this study can be useful for further studies in health product commercialization by research institutes in Africa.

Another empirical contribution of this thesis is from the stagnant health technology study. Except for literature on traditional plant medicines, literature on health innovation in Africa that identifies technologies available for commercialization is limited. This study not only identified these technologies but also documented the reasons for their stagnation.

The study also contributes to the literature on what constitutes innovation in the African context. From the study on technologies it is clear that health product innovation in Africa constitutes developing products for the local settings. Some of these are new products but the majority of them are adaptations of technologies developed elsewhere to
local settings. Cost reduction is one of the major characteristics of this kind of innovation and therefore revolves more around modifying processes.

7.4.2 **Policy implications of the thesis for specific actors**

This thesis has several implications for policy-makers, academics, entrepreneurs, and funding agencies. The case studies will help inform the effective development of innovation in Africa for:

- **Policy makers**: The information from my studies can be used by governments to create policies that promote an environment that will encourage scientists to become more innovative and commercialize their research, thus creating wealth and solving health problems. Such actions may include passing legislation that will promote innovation and protect indigenous scientific inventions, and creating proper institutional culture that facilitates commercialization. Policy makers can enact legislation that prioritizes procurement of domestically developed health products by the ministry of health. There are also practical lessons that can be learned from the KEMRI case study that can be applied by the management of other research institutes in Africa. This includes establishment of institutional IP policies that clearly state benefit sharing between the institution and scientists. At the same time health research institutions in Africa can follow KEMRI’s example and establish marketing departments or product manufacturing facilities and use lessons learned from this thesis to ensure that products they develop are successfully commercialized.

The technology level study showcased stagnant health technologies that exist in Africa. By showcasing that indeed such stagnant technologies exist, the study will motivate other African governments to carry out their own technological audits to identify stagnant technologies that may be lying latent in their own backyards. It will also give them specific ideas of how to commercialize these technologies, including examples of what has worked elsewhere.
• **Academics:** Lessons learned from these studies may be transferred to other African nations and academics in similar settings who can use them as teaching case studies in their institutions. Examples include schools of business and technology transfer offices in other similar institutions.

• **Entrepreneurs:** Information gathered from these studies can be used to attract entrepreneurs as stagnant technologies so identified will present potential investment opportunities. Entrepreneurs could include venture capital firms that would want to make profit from these technologies. The information includes factors to consider before undertaking the investment, reducing the need for entrepreneurs to go to the field to look for technologies. They will thus be better informed when they make investment decisions hence minimizing risks.

• **Donor Agencies:** Donor agencies are an integral part of the health systems of these countries yet current investments are not yielding their intended outcomes. Knowledge of innovation systems of a country can enable donor agencies to take appropriate initiatives that enhance innovative capabilities, including promoting relevant scientific research, as well as promoting the establishment of dynamic linkages between institutions and the private sector. Why would they want to do this? Because these new approaches create jobs and growth and are therefore more self-sustainable than traditional approaches to international development assistance. They may also adapt new approaches to promoting commercialization, including making equity investments and providing venture capital support. One specific area that donors can support is to provide funds for a national innovation fund. In addition they can provide domestic and international training support for innovation activities including innovation management, IP training, product development and marketing.
7.4.2.1 Practical Recommendations

Based on the findings of this thesis, there are several specific practical recommendations that can be made to overcome challenges and enhance health product commercialization in Africa. These are:

i) Provision of funding by the government to enhance the country’s knowledge base. The funding includes overall investments in the education system country’s through increased support for science-based courses in institution of higher education, provision of training to scientists interested in pursuing further training in fields such as biotechnology and overall support for R & D.

ii) Establishment of innovation specific funds by the government and donors. These funds could be a) in the form of grants to support proof of concept or b) venture capital. Venture capital not only provides proof of concept funding but also provides mentorship in entrepreneurship and business management.

iii) Strategic procurement of domestically developed health products by the government. This is because it provides a market and incentivizes local innovation. Firms in the private sector, research institutions and individual scientists will be motivated to innovate as they are guaranteed of a market for their products.

iv) Establishment of innovation platforms by governments. One of the major limitations of health product commercialization in Africa is the lack of synergies and information flow between various institutions that play a role in innovation. Innovation is an interactive process with continuous exchange of ideas between various actors. Establishment of a platform that will bring together science, business and capital can go a long way to enhance product commercialization. In addition the platform will have linkages to institutions that provide support services fro innovation such as regulatory
services, IP services, marketing and business training departments of government and the private sector. Finally such a platform can act as a one stop shop for technologies. Such centres will have proof-of-concept funds, networks linking scientists and entrepreneurs, and physical centers providing shared research infrastructure.

At a practical level, the results of the study at national level have already had an impact on policy makers in Rwanda. As discussed in detail in chapter 3, a workshop was organized in Kigali Rwanda between 23rd June and 25th June 2008 during which the results of the Rwanda case study were presented back to the interviewees and to other stakeholders in Rwanda’s science based health innovation system. Following the workshop, an initiative to address needs identified in the case study to promote product commercialization in Africa emerged. This is the establishment of Life Sciences Convergence Innovation Centers (Masum et al., 2007). These proposed centers would bring together science, business and capital, and serve as “one stop shops” for private investors who wish to tap into the pipeline of domestic African technologies and support an entrepreneurial approach to innovation in Africa.

Based on the recommendations of this workshop, the Government of Rwanda decided to establish a Life Sciences Convergence Centre. An initial budget line item of 100,000 US dollars was subsequently made in its 2009/2010 annual budget to support this initiative. Since then I have been involved in developing an operational document for the convergence centre. Another workshop held in January 2010 in Kigali resolved to temporarily host the centre at the Ministry of Education and identified three projects to be developed by the centre on a pilot basis. I assisted in carrying out due diligence on these projects and drawing the grant award. I am currently involved in providing advice on the management of the centre. At the time of writing this thesis which is still in the initial stages of being established.
Concluding remarks

This thesis was conducted as part of my desire to understand health innovation in sub-Saharan Africa. Prior to this, I really didn’t understand the concept of health product development in Africa despite the fact that I had worked as a research scientist in a public research institute in Kenya. Listening to the narratives and experiences of my fellow African scientists’ unravelled information that I never knew existed, most of which I have narrated in this thesis. My career and life has therefore been greatly enriched through this thesis.
REFERENCES


ANDI. (2009). *Strategic and business plan for the african network for drugs and diagnostics innovation (ANDI)*. Unpublished manuscript.


ANSTI. (2005). *The state of science and technology training institutions in Africa*


Feinson, S. (2003). National innovation systems overview and country cases. *D.Sarewitz, Et Al., Knowledge Flows, Innovation and Learning in Developing Countries, the Center for Science, Policy and Outcomes at Arizona State University,*


Godin, B. (2007). *National innovation system. the system approach in historical perspective project on the history and sociology of STI statistics. working paper no. 36.*


Juma, C., & Yee-Cheong, D. L. (2004). Interim report of task force 10 on science, technology and innovation. *Millennium Project Commissioned by the UN Secretary General and Supported by the UN Development Group,*


Lundvall, B. Å. (2010). *National systems of innovation: Toward a theory of innovation and interactive learning* Anthem Pr. UK


UNCTAD. (1996). "UNCTAD’s science, technology and innovation policy reviews". *Science and Public Policy, Vol. 23*(6)


WHO. (2010). *Same-day-diagnosis of tuberculosis by microscopy: World health organization:policy statement*


Won, Y. (2004). The effective way to facilitate the technology transfer from public laboratories: Spinning off the new start-ups businesses.


APPENDICIES

Appendix A: Study invitation letter Rwanda case study

Dear Sir/Madam,

We are writing to invite you to participate in a study we are undertaking on strengthening Rwanda’s health innovation system. The University of Toronto’s McLaughlin-Rotman Centre (MRC) and the Science Technology & Innovation Program at The Kennedy School of Government at Harvard University have been studying ways in which developing countries can harness modern biotechnology/life sciences for improving health. Both groups have significant experience in this field through work in Cuba, Brazil, South Africa, Egypt, India and China, and through contributing to the UN Millennium Development Project.

The goals of our study are to strengthen the country’s health innovation system and to position Rwanda as a key player in regional biotechnology development. We will do this through a comprehensive set of recommendations and strategic advice.

Our work will focus on the following key areas - health biotechnology innovation systems; innovation system link to health care system; domestic private sector development; legal system and regulatory policies; economic environment; capacity strengthening for research and development; resources for research and development; collaborations; diaspora connections; link to traditional medicine and ethical, social and cultural issues.

We are very interested in your insights and thoughts with respect to the above themes. We hope that you will accept our invitation to participate in this study.
Yours Sincerely,

Research Project Title
HEALTH BIOTECHNOLOGY INNOVATION SYSTEM

Background and Purpose of Research
The University of Toronto’s McLaughlin-Rotman Centre (MRC) has been studying ways in which developing countries can harness modern biotechnology/life sciences for improving health.

Invitation to Participate
You have been invited to participate in a one-on-one face-to-face interview. You will be asked about your views on how to strengthen Ghana’s Health Innovation System to that it can develop new products and services that meet local health needs.

Participation
Participation in research is voluntary. You are free to choose to participate or not to participate in this research study. If you agree to participate in this study, you may choose to withdraw your participation at any time. You may also refuse to answer any specific questions without any adverse consequences.

**Procedures**
You have been invited to participate in a one-on-one face-to-face interview that will last approximately 30 minutes to one hour. The interview will be conducted by the investigators and or collaborators (see list below) and will be digitally recorded and transcribed.

**When and where will the study take place?**
This work is being carried out from January 1, 2008 to December 31, 2008, at MRC, Harvard, and through fieldwork in Ghana.

**Risks and benefits of the study**
The foreseeable risks are the potential that we will disclose what you tell us and attribute it to you. You should not disclose any proprietary information to us. The potential benefit is you will help formulate policy recommendations that will strengthen Ghana’s health biotechnology innovation system.

**Privacy and Confidentiality**
The one-on-one interviews will be digitally-recorded and transcribed. All digital files and transcripts will be kept on a password-protected computer with access restricted to the research team. All field notes will be stored in a locked cabinet at the MRC. We will assume that we can attribute direct quotations from you unless specified otherwise (see consent form). All raw data (audio digital files and transcripts) will be stored in a locked cabinet, and only members of the research team at the MRC will have access to them. Confidentiality can only be guaranteed to the extent permitted by law.

**Publication of Research Findings:**
We will write a report for the Ghanaian Government and publish our results in the appropriate peer-reviewed academic journals, policy briefs, and possible teaching materials. We will present the data at national and international conferences. In publications, we may identify you by name unless you ask us to only list you among interviewees. Following the completion of our analysis, we may contact you to make sure we captured your quotes correctly (referred to as ‘member check’).

**Compensation/Remuneration**
You will not be compensated for your participation.

**Your rights as a Participant**
You waive no legal rights by participating in this study. If you have any questions about your rights as a research participant, you may telephone the Director of the Research Ethics Review Office at 416-946-3389
You are being given a copy of this information sheet.

**STUDY CONSENT FORM**

I, ______________, agree to participate in a study the diagnostic study of Ghana’s health innovation system.

By signing this form, I am indicating that I:

1. Read and understood the Letter of Invitation and the Study Consent Form, including the project rationale, description, methodology, research team, and funding, as described therein.
2. Understand that the procedure involves open-ended (face-to-face) interviews with the study investigators and that interviews will be digitally recorded and transcribed.
3. Understand that the information provided during this consultation may be used in academic publications, policy briefs, teaching materials and public presentations.
4. Understand that the only risk in participating in this study is the potential that what I say will disclosed and attribute to me. I understand that I should not disclose any proprietary information.
5. Understand that I can withdraw from the study at any time without explanation.
6. Have not waived any of the legal rights that I have as a participant in this research study after signing this form.
7. Have been given a copy of this consent form and the study information form.

If you do not wish to have your quotations attributed to you please initial here…………

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Appendix B: Study information letter. Stagnant technologies

COMMERCIALIZATION OF STAGNANT HEALTH TECHNOLOGIES IN AFRICA:

Background and Purpose of Research

Thank you for agreeing to consider participation in this research study. The objectives of this research project are:

i) To describe stagnant health technologies in Africa’s research institutions as well as the stage of development of these technologies.

ii) To describe the uses and applications of such technologies to enable stakeholders make an informed decision on the commercial viability or social usefulness of investing in these technologies.

iii) To evaluate the costs and performance of these technologies vis a vis other technologies with similar functions. This will provide information on whether there are any comparative economic advantages of these technologies.

iv) To provide a holistic overview of institutional culture and government policy and how they affect product development in Africa’s research institutes. Through in-depth studies on how various mechanisms within an innovation system interact, it will be possible to develop appropriate mechanisms to scale of ideas and inventions developed in these institutions. Such mechanisms will include finance, legal and regulatory factors, market factors as well as cultural factors.

The chief benefits to participation include the potential of exposure of the stagnant health technology to entrepreneurs and donors agencies who may be interested in scaling up the production of a particular technology that has a health impact. This is because we will distribute our work through various forums that attract diverse audiences including academics, biotechnology companies and donor agencies.

Invitation to Participate

You have been invited to participate in an interview, in which you will be asked about your perspectives and experiences with health product development projects.

You are free to choose to participate or not to participate in this study. If you agree to participate, you may refuse to answer any specific questions without any adverse
consequence. Likewise, you may later choose to withdraw your participation at any time prior to study publication without explanation.

**Procedure**

The interview will be scheduled to take place at a time and location that would be most convenient to you, and will be audio-recorded and transcribed.

With your permission, we may video record your interview for use in research outputs, presentations, edited films, or other media, as one of the tools for dissemination of the findings of this research initiative.

**Privacy and Confidentiality**

Confidential proprietary information for products will not be included in the study, and our research team will sign no non-disclosure agreements or similarly binding legal documents.

In publications/presentations reporting the findings of this study, we may identify you by name in association with to your views or specific quotations. You may also be identifiable through your appearance in recordings, if these are used in any final presentations. Should you indicate a preference to not to be so identified, you will be listed on a list of interviewees, but not attributed in any medium. We will provide the opportunity for participants to preview any attributable quotes in our final case study material before publishing.

All collected data and associated materials (e.g., audio-digital recordings, video recordings, interview transcripts, field notes, etc.) will be stored for a period of five years from the close of the study. Data and materials will be locked in a secure cabinet in our research offices in Toronto to which only members of the research team will have access. Likewise, all electronic files pertaining to this study will be stored on password-protected computers with access restricted to the research team.

A foreseeable risk to participation in this study is the possibility of breach of confidential and sensitive information, such as trade secrets and proprietary information. To eliminate this risk, we ask you to not disclose any confidential or proprietary information.

**Compensation**

There will be no financial or other compensation for participation in this study.

**Dissemination of Findings**

As a participant in this research study, we will send you a copy of the final report.
Your Rights as a Study Participant

You waive no legal rights by participating in this study.

If you have any questions or concerns about this research, you may contact Kenneth Simiyu, Graduate Student, McLaughlin-Rotman Centre for Global Health by email at ken.simiyu@mrcglobal.org or by telephone at +1.416.673.6565.

Alternatively, if you have questions about your rights as a research participant, please contact Jill Parsons (Health Sciences Ethics Review Officer, Ethics Review Office, University of Toronto) by email at jc.parsons@utoronto.ca or by telephone at +1.416.946.5806.

You are being provided a copy of this Study Information Letter to keep for your records.

Thank you.

CONSENT FORM

COMMERCIALIZATION OF STAGNANT HEALTH TECHNOLOGIES IN AFRICA:
I, ____________________________, agree to participate in the above-named research study.

(name of interviewee)

1. By signing this form, I am indicating that:
2. I have read and understood the Study Information Letter.
3. I understand that my participation involves taking part in an interview with members of the research team, and that the interview will be audio-recorded and transcribed.
4. I understand that, unless I indicate otherwise on this Consent Form, my participation in the study may be video-recorded. Such video recordings may be potentially used for video presentation as one of the dissemination tools of the findings of this research initiative, and for further research on themes related to health product development by members of the research team.
5. I understand that the data collected during interviews may be used in academic publications, policy briefs, teaching materials and public presentations.
6. I understand that the only risk foreseen by the researchers from my participation in this research study is the potential that what I say will be disclosed and attributed to me. I understand that I should not disclose any proprietary information.
7. I understand that I can withdraw from the study at any time prior to publication of study findings without explanation.
8. I understand that in signing this consent form I have not waived any of my legal rights as a research study participant.
9. I have been provided a copy of this Consent Form and the Study Information Letter.

You may check and initial any options that apply below:

☐ I DO NOT give permission to be linked to specific quotations or views that I express.

☐ I DO NOT give permission for my interview to be video-recorded.

Initials: __________

Participant’s Printed Name ____________________________________________________________________________________________
Participant’s Signature ____________________________________________________________________________________________
Date __________________________________________________________________________________________________________

Investigator’s Printed Name ____________________________________________________________________________________________
Investigator’s Signature ____________________________________________________________________________________________
Date __________________________________________________________________________________________________________
## Appendix C: Interviewees and organizations for Rwanda case study

<table>
<thead>
<tr>
<th>Organization</th>
<th>Number of Organizations</th>
<th>Number of Key Informants Interviewed</th>
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<tbody>
<tr>
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<td>5</td>
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<tr>
<td>Regulators</td>
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<tr>
<td>Educational Institutions</td>
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<tr>
<td>Non Governmental Organizations</td>
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<td>Private Sector</td>
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<tr>
<td>Diaspora</td>
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Appendix D: Interviewees for stagnant health technology study

**KENYA**

<table>
<thead>
<tr>
<th>Institution</th>
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<tbody>
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<td>University of Nairobi</td>
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<tr>
<td>Moi University</td>
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<td>KEMRI</td>
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**NIGERIA**

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<tr>
<td>University of Ibadan</td>
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</tr>
<tr>
<td>University of Benin</td>
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</tr>
<tr>
<td>NIPRID</td>
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<tr>
<td>KEMRI</td>
<td>8</td>
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**UGANDA**

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<td>Makerere University</td>
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<tr>
<td>National Chemotherapeutics Agency</td>
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**TANZANIA**

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<tr>
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<td>NIMRI</td>
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**RWANDA**

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<tr>
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<td>ISAR</td>
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<td>TRAC</td>
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<td>Ikerezi</td>
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**GHANA**

<table>
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<tbody>
<tr>
<td>University of Ghana/Noguchi Memorial Institute</td>
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<tr>
<td>University of Ghana medical school</td>
<td>2</td>
</tr>
<tr>
<td>University of Ghana-School of public health</td>
<td>1</td>
</tr>
<tr>
<td>Centre for traditional medicine</td>
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</tr>
</tbody>
</table>
Appendix E: Interview Guide for the Rwanda case study

1. Please describe what your role has been in the development of health biotechnology in Rwanda.

2. Who are the main actors in the health biotechnology sector in Rwanda? Could you please expand and describe the role of each of them?

3. Please describe the legal and regulatory environment in Rwanda. Do you feel it encourages or impedes the development of health biotechnology?

4. Please describe the intellectual property environment in Rwanda (incentives, barriers, influence on research prioritization etc.)

5. How do you feel that the financial and macroeconomic environments in Rwanda influence biotechnology development?

6. Could you please tell me if and how your institution/firm is linked with other institutions and firms in the biotechnology sector? If so, to which institutions?

7. Please tell me if and how your institution/firm is linked with institutions and firms in the domestic biotechnology sector in other countries or with international organizations? If so, to which institutions?

8. Could you tell me about some examples of successful health biotechnology products and services from your country?

9. Could you tell me more about the capabilities (research, manufacturing etc) of your institution/firm?

10. How receptive to or educated biotechnology is the public in Rwanda, in general?

11. Please discuss the issue of brain drain of Rwanda’s skilled professionals.

12. What do you think are the crucial elements which have contributed to the success of the health biotechnology system?

13. What are the major barriers impeding the development of the health biotechnology system?

14. What do you see as the role of health biotechnology in your country both in the context of health delivery and public health? (health delivery e.g. more appropriate diagnostics – public health e.g. higher life expectancy)
15. What do you see as the role of health biotechnology in your country in the context of the wider national economy?

16. What you consider to be the major forces that impact upon and shape the appropriate adoption of new health technologies in developing countries?

17. How would you improve the situation in your country to encourage health biotechnology development further?

18. What do you think about the prospects of the health biotechnology sector in your country? Are you optimistic or pessimistic? Where will it be in 5 to 10 years?
Appendix F: Interview guide stagnant technologies

NB: while this interview guide will provide a common baseline across all case studies, field investigators are expected to spend the majority of their time on case-specific questions. As investigators learn about the particular context of each technology and organization, they will probe more deeply into particular attributes that make up the technology. Similarly, interviewees will be asked questions specific to their position and background. The questions have been divided into sections as applies to different interviewees.

To be answered by individual scientists:

Technology identification and general description

1. Please describe the uses and applications of your technology and how the idea arose?
2. Please tell us the story of how the technology has developed thus far and what is the current stage of development?
3. Do you know whether alternative competitor products exist and if so, what advantages, if any, does this product have over existing products?
4. What will be your route to commercialize the technology?
5. If you have already attempted to commercialize the product what was your experience? Who were the major players involved and how did their interaction impede or promote the product's development?
6. What challenges do you face in accessing capital?
7. How did you acquire the expertise to develop this product? How many people are involved in developing it?
8. What external institutions, programs, or individuals helped this technology development to succeed?
9. What other projects are you working on are have you worked on in the recent past?

Details on the technology

1. Briefly describe how the technology works.
2. What is the intellectual property status of the product? What is the IP policy at your organization? Could you describe your experience in licensing this product?
3. Is it possible to scale up this product/technology? If so, what attribute does your technology have that would make it attractive for scaling up?
4. What do you need to take the technology to the next step of commercialization i.e. Technology development, capital, collaboration and partnerships?

Health Impact and Product Market
1. What is the potential health impact of this technology? How do you measure this impact?
2. Which is the potential market of this technology? Local or Global and approximately how big is the market size?

Transferable Lessons

1. If you could go back in time in your technology development process, what would you do differently, and why?
2. What advice would you give to scientists thinking of developing a health product in Africa?
3. What advantages or what difficulties do you face as a scientist trying to develop an invention while being located in a developing country?
4. What information, knowledge, or tools would be most useful to you in the challenges you currently face?

To be answered by institutional management:

Organization Background

1. Please describe your organization’s focus, including core technologies, services, and products.
2. What proprietary technologies does your organization possess?
3. What alliances does your organization have?
4. What criteria do you use to decide which products and opportunities to focus on? Have these criteria changed since your organization was started?
Appendix G: Workshop Summary

This workshop was convened in partnership between the Rwanda Science and Research Council and the University of Toronto, Canada’s McLaughlin-Rotman Centre for global health. The workshop had two main objectives: 1) Officially launch the Rwanda Science and Research Council and develop a strategic guide for the council and 2) Explore the theme of impacting socio-economic change through knowledge, research, science and technology-led initiatives.

About eighty scientists drawn from all Rwanda’s scientific research institutions in all fields participated in the three-day workshop held at the Novotel, Kigali between 23rd, June and 25th June, 2008. In addition to scientists, other participants included the World Bank, international scientists, a team from the McLaughlin-Rotman Center for global health, Canada and members of Rwanda’s private sector.

The Rwanda Science and Research Council was formally established in January 2007 with four specific objectives: (a) to promote research, science and technology; (b) to encourage Rwandans to take advantage of science and research outputs in the development process; (c) to develop capabilities of national scientists and researchers; (d) to facilitate partnerships between the Rwandan scientists and researchers with their counterparts abroad. RSRC believes that there are numerous uncoordinated, untargeted and on-impact oriented research initiatives in the country and that there is rich, unknown pool of knowledge and skills which remain underutilized within and outside Rwanda which can be tapped.

Last year, the World Bank conducted a Needs Assessment study on critical areas identified in the Government of Rwanda’s Science, Technology and innovation policy and its report was presented to the workshop. The report recommends specific action plans that are practical and solve some of Rwanda’s main economic problems. In addition, towards the end of last year, the Government of Rwanda invited researchers from the McLaughlin-Rotman Centre for Global Health in Toronto, to undertake a study of Rwanda’s life sciences innovation system and review ways in which the potential can be harnessed to improve food security, create jobs and wealth to enhance affordable health care delivery and have a sustainable environment. A 'Convergence Centre' was proposed to act as a platform for bringing together all the members involved in Rwanda's innovation system, including: policy makers, research institutions, capital providers, the private sector and donor groups. Scientific institutions and individual researchers can share specialised laboratories and equipment and will be co-located with entrepreneurs, investors, financiers and government policy makers, creating 'a one-stop shop' where their ideas can be developed into market ready products. During the workshop, the concept of the convergence center resonated well with those present and an action plan to develop a business plan was proposed.

Presentations were also made that demonstrated appropriate technologies that can be developed and used in Rwanda.

The key outcomes of the workshop are as follows:
1. Development of a strategic guide for the RSRC.
2. Development of a business plan for the convergence center.

The workshop came up with specific action plans to follow-up on these outcomes. The workshop concluded that there is need for better coordinated activities between Rwanda’s scientific community to enhance the country’s economic growth.